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IMMAGE® 800 Immunochemistry System

Instructions For Use
For *In Vitro* Diagnostic Use

EC REP
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CHAPTER 1 General Information

Introduction

Intended Use

The Beckman Coulter IMMAGE® 800 Immunochemistry System (Refer to Figure 1.1.) is a fully automated, computer controlled, bench-top analyzer designed for the in vitro quantitation of biological fluid components and therapeutic drugs. The system methodologies are rate turbidimetry and rate nephelometry.

The IMMAGE 800 is a high throughput, random access analyzer that features bar code identification of samples and reagents to perform sample testing. It automatically dilutes the samples and delivers them to the reaction cuvette along with other reaction constituents. The system analyzes up to 72 samples per run with up to 24 analytes per sample.

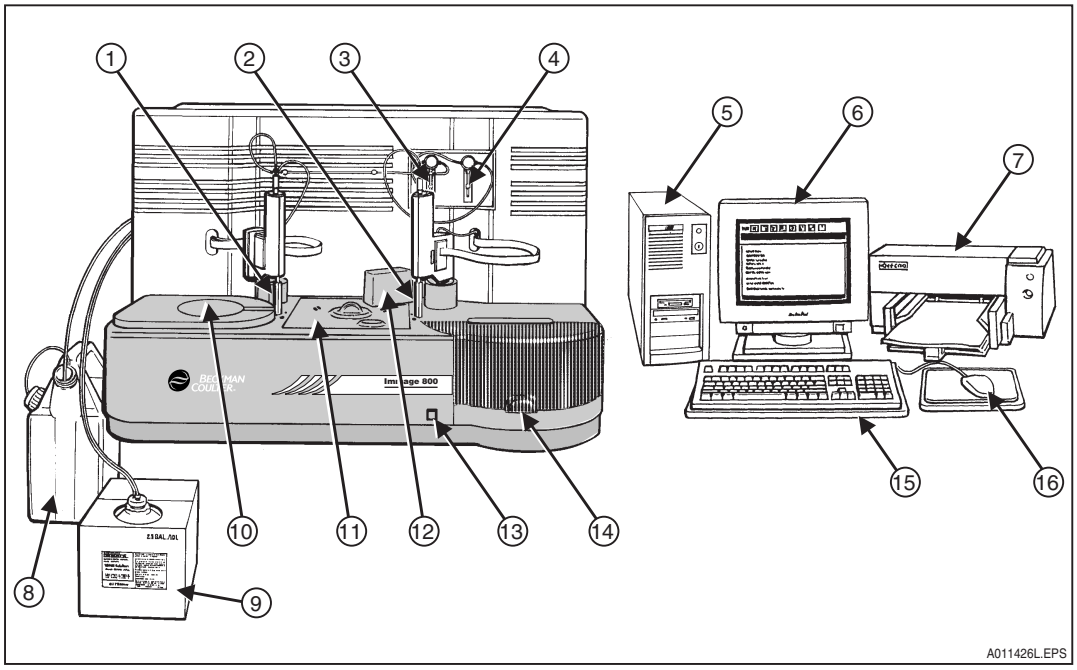
Scope of Manual

This manual provides information on the operation of the IMMAGE 800. Diagnostic interpretation or the clinical significance of the assay results provided by the system are not discussed in this manual. Typical and actual results are shown only to demonstrate the operating procedures, parameters, and characteristics of the system.

Reference Materials

Detailed information is available in the following manuals that accompany the IMMAGE 800 Immunochemistry System. Those manuals include:

- IMMAGE 800 Immunochemistry System *Operations Manual*. This manual contains a detailed system description, comprehensive operating instructions, theory of operation, system calibration and programming procedures, and quality control information for the IMMAGE 800 analyzer.
- IMMAGE Immunochemistry Systems *Chemistry Information Manual*. This manual contains specific chemistry information for the full range of analytes available on the IMMAGE 800 analyzer.
- IMMAGE Immunochemistry Systems *Host Interface Specifications*.
- IMMAGE Immunochemistry Systems *Sampling Template*.



1. Reagent Probe and Mixer
2. Sample Probe and Mixer
3. Reagent Syringe
4. Sample Syringe
5. Computer
6. Monitor
7. Printer
8. Waste Container
9. Wash Solution
10. Reagent Compartment
11. Reaction Module
12. Cuvette Wash Station
13. Advance Button
14. Sample Carousel
15. Keyboard
16. Mouse
17. Uninterruptible Power Supply -not shown

Figure 1.1 IMMAGE 800 Immunochemistry System

Shipping Damage

Each IMMAGE 800 System is carefully examined and checked by Beckman Coulter before it is shipped. When you receive your new IMMAGE 800 System, visually inspect the shipping container for any possible damage, It there is damage, notify the Beckman Coulter Service Representative before his/her arrival at your facility to install your system.

If no damage is found to the shipping container, the Beckman Coulter Service Representative will supervise the unpacking of your system. If there is damage in any way, the customer should file a claim with the carrier. If no damage is found, a visual and operational check of your system will be performed.

Precautions And Hazards

Precautions

- Do not store or place a diskette near electrical motors, power supplies, generators, magnets, or magnetic fields.
- Hold a compact disk (CD) by the edges and replace it in its case after use. DO NOT place a CD in direct sunlight or excessive heat or humidity.
- Sample containers must contain an adequate volume of test specimen to ensure accurate aspiration.

Hazards

- Connect the three-pronged power plug from all system components of the IMMAGE 800 Immunochemistry System to a three-wire grounded power source. DO NOT use an adapter to connect the power plug to a two-pronged outlet. If the electrical outlet will not accept the three-pronged plug, notify a qualified maintenance personnel.
  UNDER ANY CIRCUMSTANCES, DO NOT OPERATE THE SYSTEM UNTIL AN ELECTRICAL GROUND IS PROVIDED AND THE POWER CORD IS PROPERLY CONNECTED TO GROUND.
- Close reagent and sample carousel covers and keep clear of all mechanical assemblies when booting up the system.
- Keep clear of both cranes while the instrument is running.
- Keep all covers and shields in place while the instrument is running.
- Confirm that the instrument status is *Standby* when adding or changing reagents, buffers, diluents, or dilution segments. The instrument status must be in *Standby* or "Pausing-OK to load samples" when adding or removing samples. Keep reagent and sample carousel covers closed while the instrument is running.
- Confirm that the system is turned off before replacing any defective mechanical or electrical part in the system.
- DO NOT tamper with or remove the housing of any bar code reader.
- Dispose all waste liquids from the IMMAGE 800 Immunochemistry System in an approved method for handling biohazardous material.
- Observe all laboratory policies or procedures pertaining to the handling of biological samples that may contain pathogens.
- To **EMERGENCY STOP,** turn the instrument main power switch off if the stop button on the screen is unavailable, and the instrument must be stopped immediately.
- **PRESERVATIVES:** Sodium azide preservative may form explosive compounds in metal drain lines. See National Institute for Occupational Safety and Health bulletin: Explosive Azide Hazards (8/16/76).
- Incineration of used reagent cartridges may produce toxic fumes.

Symbols and Labels

High Voltage-Electric Shock Risk

This symbol indicates high voltage or risk of electric shock.

High Voltage-Electric Shock Risk

Read Manual

This symbol cautions that the manual should be read before using the system.

Read Manual

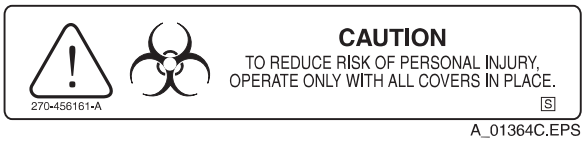
General Biohazard Caution

This symbol is the international symbol for biohazardous material.

Biohazard Label

Caution Biohazard

This cautionary label is located between the sample and reagent carousels. Operate the system with all covers in place.



Caution Biohazard Label

Barcode Caution Label

This label is placed on the cover of any laser-based bar code reader. Do not stare into laser light beam when cover is open or removed.

Bar Code Caution Label

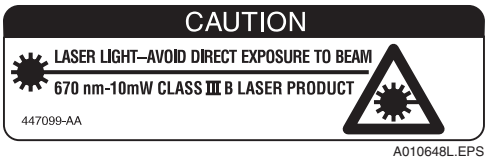
Laser
This label is placed near any opening through which a bar code reading beam emits. Avoid exposure to laser light emitted from the opening.

Laser Caution Label

Class II Laser Caution
This cautionary label is located between the sample and reagent carousels. Do not stare into laser light beam.

Class II Laser Caution Label

Class III B Laser Caution
This cautionary label is located at the top of the optics module. Avoid direct exposure to laser light beam.



Class III B Laser Caution Label

Compartment Cover Notice
This label is located on the reagent compartment cover. The instrument will stop if the cover is opened.

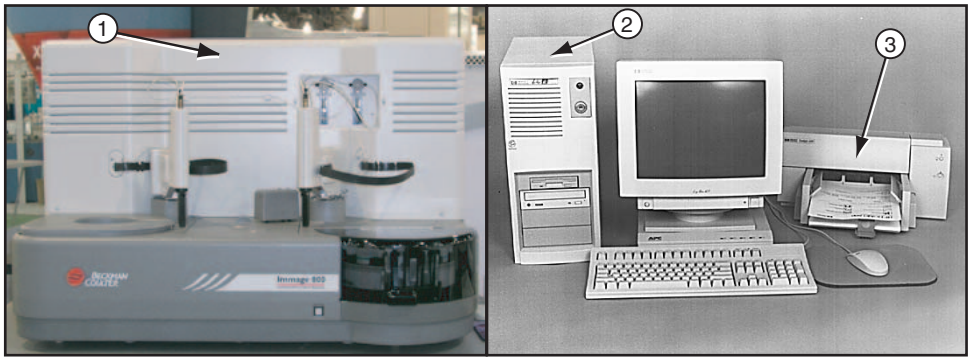
Reagent Compartment Cover Label

CHAPTER 2 System Description

System Description

Introduction

The IMMAGE® 800 Immunochemistry System is a bench-top analyzer composed of the IMMAGE 800 instrument, computer and printer. (Refer to Figure 2.1.) The system is shipped complete for installation. The system will be installed by a Beckman Coulter Representative.



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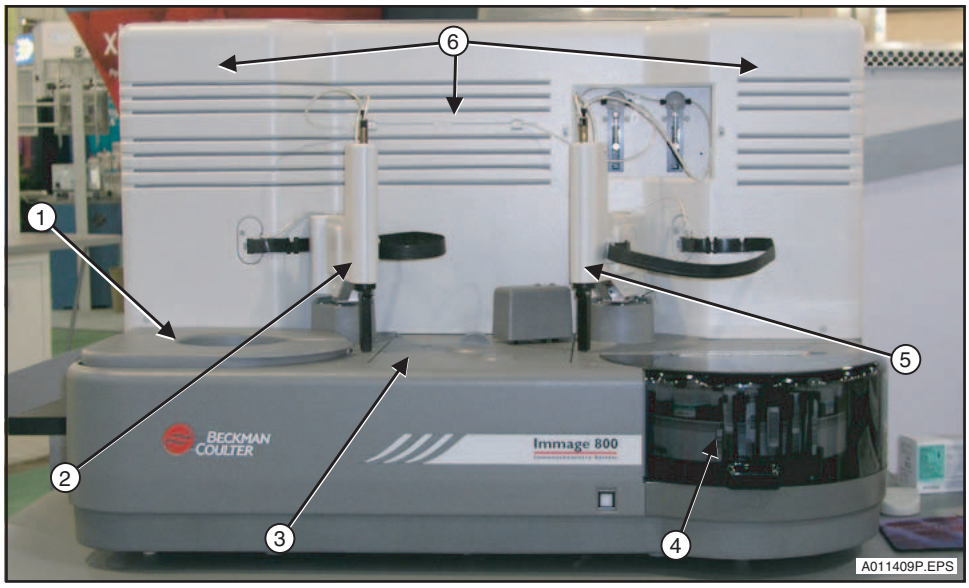
1. Instrument
2. Computer
3. Printer

Figure 2.1 The IMMAGE 800 Immunochemistry System

System Components

IMMAGE 800 Instrument

The IMMAGE 800 *instrument* is the analytical unit where the samples and reagents are loaded and where the chemical reactions take place. (Refer to Figure 2.2.)



1. Reagent Compartment
2. Reagent Crane
3. Reaction Module
4. Sample Carousel
5. Sample Crane
6. Upper Instrument Subsystems
7. Sample Carousel Advance Button

Figure 2.2 IMMAGE 800 Instrument

Computer

The computer supplies the user interface to the IMMAGE 800 Immunochemistry System and stores data.

The user performs all software interaction in the computer portion of the system. This software interaction is stored in the computer and is sent to the instrument at the appropriate time.

Additionally, patient results, control results, and setup parameters are stored in the computer.

> NOTICE
> Only the computer supplied by Beckman Coulter is to be used with the IMMAGE 800 Immunochemistry System.

Changing the Date on the PC

The PC supplied with some IMMAGE 800 system contains a battery that provides power to the computer's internal clock during power off. The status of the battery is checked every time the Power On sequence is performed.

> **⚠ CAUTION**
>
> **The date and time must be reset each time the Power On sequence is performed on a computer with a dead CMOS (Complementary Metal Oxide Semiconductor) battery. Contact Beckman Coulter Clinical Support or the nearest local Beckman Coulter Field Service office for assistance in replacing the battery.**

Printer

The printer supplied with the IMMAGE 800 Immunochemistry System is a Hewlett Packard DeskJet printer. The printer is designed to use single sheet paper.

The printer is set up to use 8.5 × 11 inch paper. Paper size can be chosen in **Printer Setup**.

Program Structure

The software or interface of the IMMAGE 800 Immunochemistry System is divided into functional areas based on different tasks. The icons in the menu bar at the top of the screen represent the various functional areas.

The MAIN operator screen consists of:

- Stop - Instrument stops immediately
- Home - Reagents, sample carousels, cuvettes and probes return to the home position
- Pause - Instrument stops after current samples are completed
- Run - Starts a run

System Specifications and Characteristics

Instrument Specifications

Placement

The surface on which the unit rests must be free of vibration and must be level, 1° or <0.75 inch (1.9 cm) slope across the length and the width of the instrument. Do not place instrument in direct sunlight or drafts or near a heating or cooling duct.

Clearance
Sides: 6 inches (15.2 cm) minimum
Back: None
Front: 3 inches (7.6 cm) minimum
Top: 4 inches (10.1 cm) from top of instrument

Dimensions (Excluding Wash and Waste Bottles)

Height = 30 inches (76.2 cm)
Depth = 25.5 inches (64.8 cm)
Length = 43.5 inches (110.5 cm)

Weight

250 lb. (120 kg)

Power Requirements

Operating Range	115 (90 to 132) VAC RMS, Single Phase 230 (180 to 264) VAC RMS, Single Phase
Frequency	50/60 Hz nominal (47 to 63 Hz)
Transient Suppression	Recommended
BTU Generated	2,900 BTU/hour
Electrical Outlet	Grounded per Local Code
Surge Protector	Recommended
Current	8.0 Amps (normal) 12 Amps surge

Temperature and Humidity

Ambient Temperature	+15°C to +32°C
Ambient Relative Humidity (RH)	15% to 85% (non-condensing)
Reagent Compartment Temperature	+13°C to +22°C (+32°C Ambient, <45% RH)
Reaction Module Temperature	+37°C ± 0.5°C

Environmental Conditions

System can operate up to 8000 ft (2,438m) elevation.

Drain Requirements

Flow Rate: 3 Liters/hour minimum
Waste Container Placement: The opening should be no higher than the top of the instrument.

Regulatory Agency Approvals

The IMMAGE 800 meets the safety requirements for the following agencies: CE, UL, CSA, IEC and CENFLEC.

Environmental Conditions

System can operate up to 8000 ft. (2,438m) elevation.

Capacities

The following table lists various system capacities.

Table 2.1 System Capacities

Item	Capacity
Reagents	24 reagent cartridges can be loaded.
Reagent cartridge	40, 150, or 300 tests per cartridge.
Reaction buffers	4 bottles can be loaded.
Buffer bottle	120 mL: 350 tests.
Samples	72 samples can be loaded.
Sample diluents	4 bottles can be loaded.
Diluent bottles	120 mL: number of dilutions is workload dependent.
Sample dilution segments	4 segments of 36 wells each.
Dilution well	300 µL.

(1 of 2)

Table 2.1 System Capacities, continued

Item	Capacity
Wash solution	1 box/10 L/approximately 1,000 tests.
Waste container	5 gallons (18.9 L).

(2 of 2)

Sample Container Information

Sample Containers Allowed

Introduction

The following categories document specifications for sample containers that can run on the IMMAGE 800 Immunochemistry System.

Primary Tubes

16 × 100 mm (10 mL)
16 × 75 mm (7 mL)
13 × 100 mm (7 mL)
13 × 75 mm
16.5 × 92 mm

Secondary (Aliquot) Tubes

16 × 100 mm
16 × 75 mm
13 × 100 mm
12 × 75 mm

Microtubes

13 × 100 mm SYNCHRON® Microtube™

Sample Cups

NOTICE

Low humidity and high ambient temperature may cause evaporation when using small volumes of sample in sample cups. To minimize evaporation:

- Program samples in positions A or B on the sample carousel, or
- Program samples as STATS.

2 mL (placed into a sample cup holder)
0.5 mL (placed into a sample cup holder)

CHAPTER 3 Theory of Operations

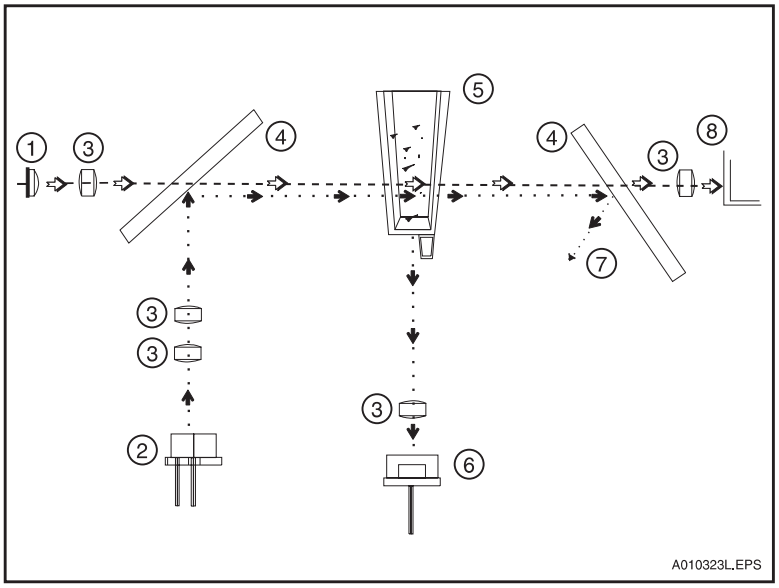
Principles of Methodologies

Principles of Rate Nephelometry

The rate nephelometer measures the increase in the intensity of light scattered by particles suspended in a cuvette. The light source for the rate nephelometer is a 670 nm laser. The detector is placed at a 90° angle from the laser beam to measure light scatter, as shown in Figure 3.1.

Principles of Rate Turbidimetry

The rate turbidimeter measures the decrease in the intensity of light as it passes through a solution of light scattering particles in a cuvette. The light source for the rate turbidimeter is a light emitting diode (LED) at a wavelength of 940 nm. Turbidimetric measurements are made at 0° from the incident beam as shown in Figure 3.1.



1. LED Light Source (Turbidimetric)
2. Laser Light Source (Nephelometric)
3. Focus Lens
4. Beam Splitter
5. Reaction Cuvette
6. Nephelometric Detector (90° angle to incident laser beam)
7. Laser Light Bounces Into Light Trap
8. Turbidimetric Detector (0° angle to the incident LED beam)

Figure 3.1 IMMAGE 800 Rate Nephelometer and Rate Turbidimeter Basic Components

Antigen Excess Testing

Overview

Antigen excess (AGXS) testing is only necessary for some IMMAGE 800 protein reagents.

Immunoglobulin G (serum IGG, urine IGU), Immunoglobulin A (IGA), Immunoglobulin M (IGM), Kappa (KAP), Lambda (LAM), Haptoglobin (HPT), Urine Transferrin (TRU), Alpha-1-Microglobulin (A1M), Microalbumin (MA) and Albumin (ALB) which are identified by the system as ambiguous, are tested for antigen excess condition if AGXS testing is enabled. A reaction is ambiguous if the rate response could represent either an antigen excess or an antibody excess reaction.

Antibody Excess

When the reaction is to the left of the optimal antibody-antigen proportions the reaction is in antibody excess (AbXS). This indicates all the antigen in the sample is bound, forming complexes. This is the ideal condition for the reaction to take place.

Antigen Excess

When the reaction is to the right of the optimal antigen-antibody proportions the reaction is in antigen excess (AgXS) and the rate response will start to decrease due to excessive levels of antigen.

CHAPTER 4 System Power On/Off

System Power On

Introduction

After the IMMAGE® 800 Immunochemistry System installation, the system can be powered on.

Power On Sequence

Follow the steps below to power on the IMMAGE 800 system.

Step	Action
1	Check that the floppy disk drive is empty.
2	Turn on the printer.
3	Turn on the monitor.
4	Turn on the CPU.
5	Verify that the UPS is on. (The UPS power switch is on and the power indicator light is on.)
6	Turn on the instrument.
7	Close reagent and sample carousel covers.
8	When the note is displayed to check dilution segment status, select **<OK>**.
9	When the temperature warning note displays, select **<OK>**. • The system will continue to bring the reagent chamber and reaction cuvettes to the appropriate temperature range. • The system will not allow a run to start until the reaction cuvettes are within the appropriate temperature range.
10	Refer to the appropriate chapters in this manual to operate the system.

System Power Off

Power Off Sequence

The instrument status must be *Standby* in order to proceed with the steps below to power off the IMMAGE 800 system.

> NOTICE
> The database may become corrupted if power is turned off before the Power Off sequence is completed.

Step	Action
1	Check that the floppy diskette drive is empty.
2	Select **Utilities** from the menu bar.
3	Select **<Shutdown>**.
4	When the message *Shutdown Complete* is displayed, turn off the printer, monitor, CPU (computer), UPS, and instrument.

Emergency Stop

Turn the instrument main power switch off if the stop button on the screen is unavailable and the instrument must be stopped immediately.

> NOTICE
> When an emergency stop or unplanned power loss occurs during a run, and power is restored within 24 hours, the cuvettes must be washed 1 time before a run can be started. (Refer to IMMAGE 800 Immunochemistry System, *Operations Manual*, Chapter 10, *Utilities*, As-Indicated Maintenance, "Washing Cuvettes.")
>
> If power is restored after 24 hours, the cuvettes must be replaced. (Refer to IMMAGE 800 Immunochemistry System *Operations Manual*, Chapter 10, *Utilities*, As-Indicated Maintenance, "Replacing Cuvettes.")

CHAPTER 5 System Software Configuration

Overview

Introduction

In System Setup several features of the IMMAGE® 800 Immunochemistry System interface can be customized for the individual laboratory's requirements. Setup maintains the default parameters used for configuring the IMMAGE 800 interface. **The instrument must be in *Standby* in order to proceed**.

This chapter includes:

- configure the chemistry menu
- set up panels
- set up bar codes
- set up reference intervals
- set up reports
- set up special calculations
- set up units/non-standard dilutions
- configure antigen excess testing
- set up date and time
- set up host communications
- set up default
- set up sample comments
- set up demographics
- set up the printer
- set up the language
- read the chemistry protocol diskette
- enter the instrument serial number
- set up user-defined reagent chemistries

Accessing Setup

Select **Setup** from the menu bar. Choose the desired setup option from a numbered button. (Refer to Figure 5.1.) Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

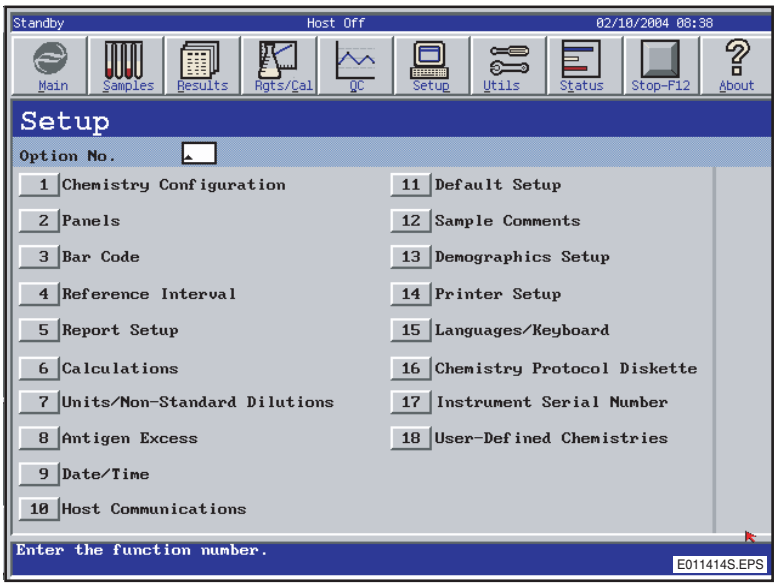


Figure 5.1 Setup Screen

Configuring the Chemistry Menu

The chemistry menu available in the sample programming, quality control, panel definition and other screens is defined by the individual laboratory. The menu contains up to 72 chemistries.

From the Setup screen, select **<1> Chemistry Configuration**.

Panel Setup

The IMMAGE 800 holds up to 50 chemistry panels in its memory. Each panel is defined with a name and the chemistries that it contains.

From the Setup screen, select **<2> Panels**.

Bar Code Setup

The bar code symbologies recognized by the IMMAGE 800 can be selected. Additionally, the bar code parameters can be configured to match those of the sample bar codes being read.

From the Setup screen, select **<3> Bar Code**. (Refer to Figure 5.2.)

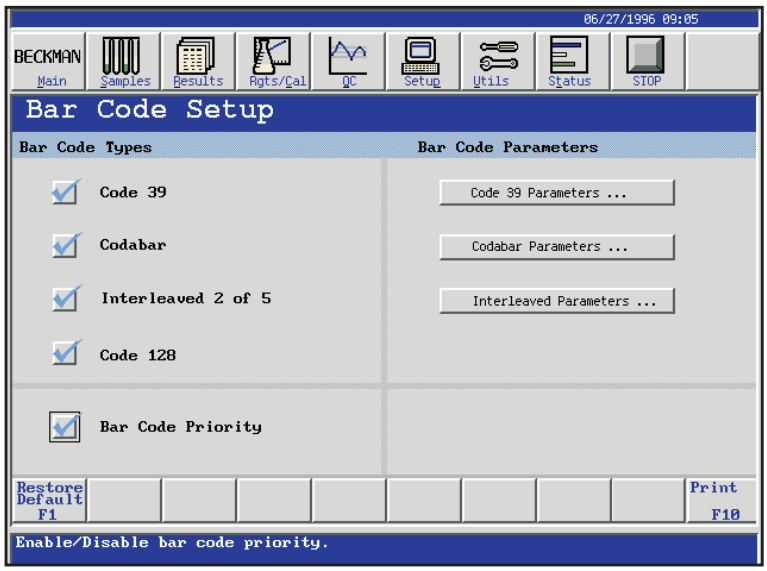


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Figure 5.2 Bar Code Setup Screen

Bar Code Priority

If the bar code priority is disabled, the batch programming WILL autonumber the racks and positions.

If the bar code priority is enabled, the batch programming will NOT autonumber the racks and positions.

- The instrument reads bar coded samples whether or not the Bar Code Priority is enabled.
- Disabling the Bar Code Priority is recommended.

Reference Interval Setup

When a reference interval and critical range are defined, they are printed beside the result on the report. A result outside of the reference interval or critical range is flagged. The interval and range are defined per chemistry or calculation with distinction made for sample type, sex, and age group.

Chemistries must be configured and calculations must be enabled before intervals can be defined.

The minimum entries necessary to save a reference interval are low age, low age unit, high age, high age unit, low reference interval number and high reference interval number.

From the Setup screen, select **<4> Reference Interval**.

Selecting the Default

The default interval and range will be printed when an age is not specified in sample programming or when age is specified but the reference interval has not been defined for that age.

Only one default can be chosen for a particular interval and range definition grouped by chemistry/calculation, sample type and sex.

Report Setup

Report formats can be selected for patient reports. A report header, including a facility name and address, can also be defined. Automatic printing of calibration, control, and patient reports can also be enabled.

From the Setup screen, select **<5> Report Setup**.

Calculations Setup

There are 12 Beckman Coulter defined calculations that can be enabled for the IMMAGE 800. The system will automatically calculate and print the final calculation on reports when the chemistries necessary for the calculation are run.

The system provides a maximum of 28 additional calculations that may be defined, edited, and/or deleted by the operator. The Custom Calculations feature provides for the reporting of operator-defined calculations using sample results when chemistries necessary for the calculations are run. The calculations may involve results from one sample or two linked samples.

The default for calculations is disabled.

From the Setup screen, select **<6> Calculations**. (Refer to Figure 5.3.)

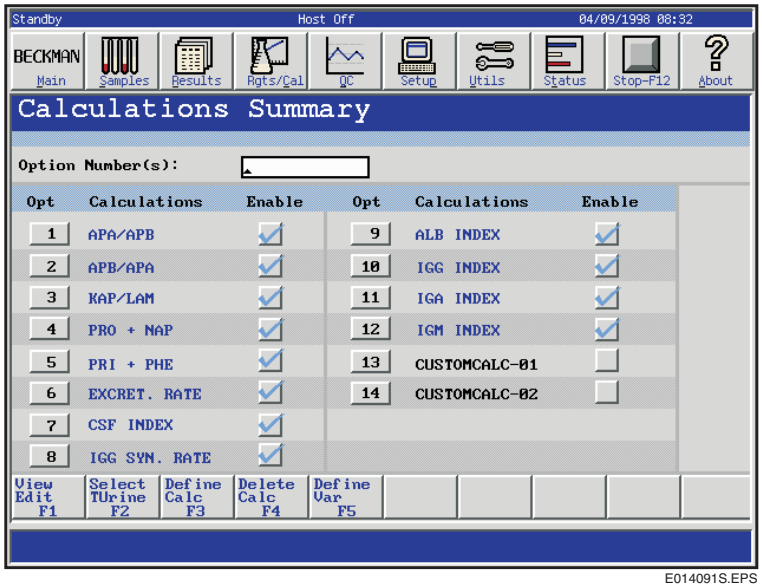

Figure 5.3 Calculations Summary Screen

Units Setup

Units can be selected for reporting with the results and displayed throughout the IMMAGE 800 system for each chemistry.

From the Setup screen, select **<7> Units**.

Selecting Non-Standard Dilutions as Default for Each Chemistry

Introduction

The instrument status must be in *Standby* in order to select a non-standard dilution for a chemistry. The system allows the user to select a non-standard dilution to use as the initial dilution every time a particular assay is run.

Selecting a Non-Standard Dilution

Step	Action
1	From the Setup screen, select **<7> Units/Non-Standard Dilutions**.
2	Select the sample type. Then select the **options button < >** beside the desired chemistry. Standard and non-standard dilutions are displayed.
3	Select the number beside the desired dilution for the selected chemistry and sample type. Note that the current default dilution is highlighted. If the chosen dilution is a non-standard dilution, that dilution will appear on the Units/Non-Standard Dilutions screen. OR Select **<Cancel>** to return to the Units/Non-Standard Dilutions screen without changing the non-standard dilution. OR Select **<Default>** to return to the standard default dilution.
4	Repeat Steps 2-3 for additional chemistries.

When a non-standard dilution has been selected for a chemistry and sample type, whenever this chemistry is run in this sample type, the system uses the selected non-standard default dilution as the initial dilution. If the test is out of range at this dilution, the system will step up or step down to a different dilution.

If the original sample was programmed to run with a standard dilution, and later you changed the default dilution to a non-standard dilution, the sample will be rerun with the standard dilution.

Configuring Antigen Excess Testing

Antigen excess (AGXS) testing can be enabled or disabled for each appropriate chemistry configured on the chemistry menu.

The default for AGXS testing is enabled for all the appropriate chemistries.

If AGXS testing is enabled, AGXS testing is always performed for the associated chemistry. If AGXS testing is disabled, AGXS testing will not be performed for the associated chemistry. AGXS can be enabled or disabled for an individual sample in Sample Programming.

From the Setup screen, select **<8> Antigen Excess**.

Date and Time Setup

At installation the system requires the date and time to be set. After this, changing the date or time is optional. The format of the date and time for the appropriate screens and printouts may be changed as well.

From the Setup screen, select **<9> Date/Time**.

Host Communications Setup

When connecting a laboratory information system (LIS) to the IMMAGE 800, several parameters must be set. These parameters should be set by the person configuring the connection between the IMMAGE and the LIS. Further information about all of the host communications parameters is found in the IMMAGE Immunochemistry Systems *Host Interface Specifications*.

From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.4.)

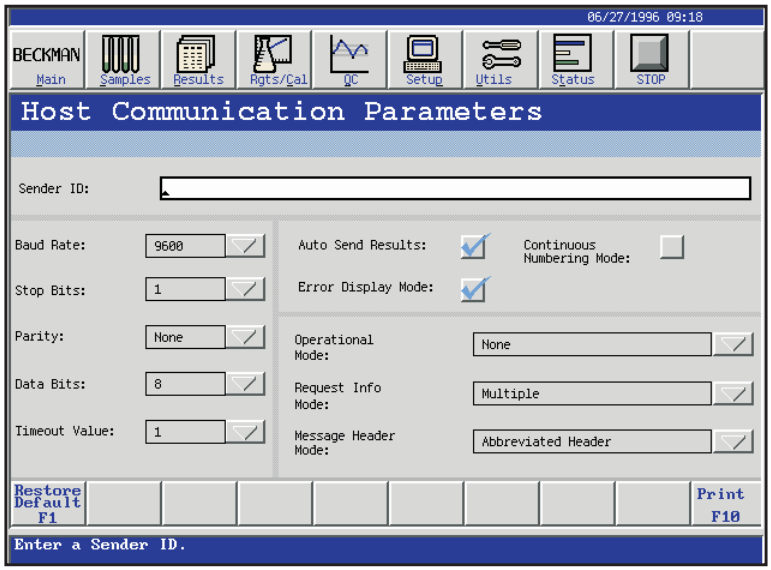

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Figure 5.4 Host Communications Parameters Screen

Default Setup

Default Setup is used to:

- define the default sample type for all samples programmed. The sample type can be changed for individual samples from the Program Sample screen.
- define the default number of replicates to be run for each sample.
- define the Post Run Summary time (none - 72 hours).

From the Setup screen, select **<11> Default Setup**.

Sample Comments Setup

Up to 20 sample comments may be predefined on the IMMAGE 800 Immunochemistry System for use when programming samples on the instrument. These will be presented in a numbered menu when programming samples.

Demographics Setup

The fields which are accessible in the demographics screen of sample programming can be selected.

To select fields to be displayed in Sample Programming, from the Setup screen, select **<13> Demographics Setup**. (Refer to Figure 5.5.)

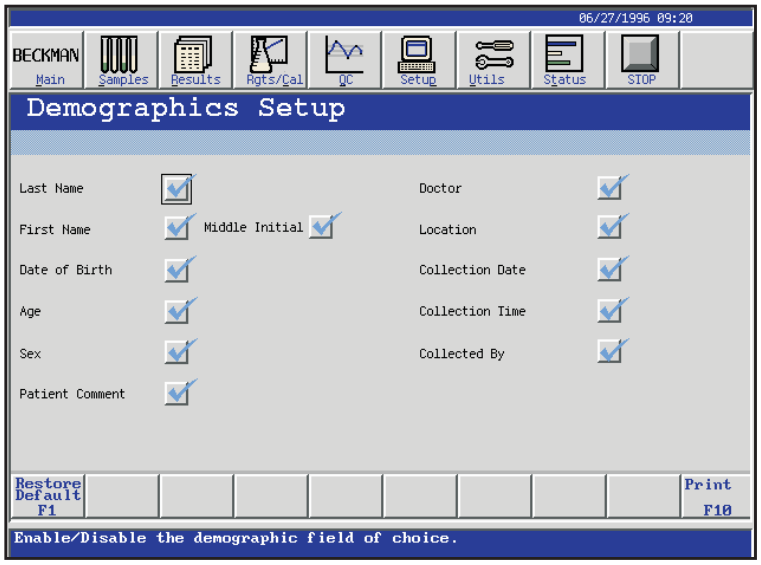

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Figure 5.5 Demographics Setup Screen

Printer Setup

The printer type is a Hewlett Packard Deskjet® or compatible. The paper size can be selected.

From the Setup screen, select **<14> Printer Setup**.

Language Setup

A language can be selected for use for system operations and printouts on the IMMAGE 800. The keyboard should match the language.

- From the Setup screen, select **<15> Languages/Keyboard**.
- Select a language from the options button **<▼>**.

> NOTICE
> Selecting Japanese from the Language options will cause the Language/ Keyboard selection to become unavailable. Reloading of the software is necessary to restore the Language/Keyboard Selection option.

- Perform the power off sequence and then the power on sequence. (Refer to IMMAGE 800 Immunochemistry System *Instructions for Use* CHAPTER 4, *System Power On/Off*, Power On Sequence, Power Off Sequence.)

Loading the Chemistry Protocol Diskette

The chemistry protocol diskette is provided with each IMMAGE 800 Immunochemistry system. It contains essential non-lot specific information about how to run each chemistry.

The chemistry protocol diskette is loaded when the IMMAGE 800 is installed. When new chemistries become available, a new diskette is provided.

From the Setup screen, select **<16> Chemistry Protocol Diskette**.

Instrument Serial Number Setup

The serial number of the instrument is entered through the Instrument Serial Number option. The instrument serial number will be printed on all reports.

From the Setup screen, select **<17> Instrument Serial Number**.

UDR Chemistry Overview and Precautions

Each laboratory can define its own user-defined reagent (UDR) chemistry protocols using the templates from the chemistry protocol diskette. After the chemistry protocol diskette is loaded and the UDR protocol is defined, the UDR chemistry name is available for placement on the list of configured chemistries for selection in UDR rate mode programming, reference intervals, UDR calibration, sample programming, control definitions and panels. Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

User-Defined Reagent Chemistry Setup

UDR Chemistry Overview and Precautions

Introduction

Each laboratory can define its own user-defined reagent (UDR) chemistry protocols using the templates from the chemistry protocol diskette. After the chemistry protocol diskette is loaded and the UDR protocol is defined, the UDR chemistry name is available for placement on the list of configured chemistries for selection in UDR rate mode programming, reference intervals, UDR calibration, sample programming, control definitions and panels.

Precautions

CAUTION

Since Beckman Coulter does not manufacture or otherwise control the sample and reagents that may be used in user-defined reagent applications, Beckman Coulter makes no warranty whatsoever with respect to such sample and reagent performance (including sample carryover, test results, reagent and cartridge handling), their effect on the system or required system maintenance or the frequency thereof, or their effect on operator safety. User assumes full responsibility for use of the proper test protocol and test result generation for the reagent(s) selected by the user and for any errors or omissions associated therewith. BECKMAN COULTER EXPRESSLY DISCLAIMS ALL WARRANTIES WITH RESPECT TO THIS PRODUCT WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

CAUTION

Non-Beckman Coulter reagents, calibrators, and controls can contain components, not listed on the insert, which may carry over into the system causing chemical or optical interference. This carryover could adversely affect results on a properly performing system. Manufacturers of user-defined reagents should be contacted for disclosure of potentially interfering substances, such as preservatives.

Setting Up a UDR Chemistry

Loading the Protocol Diskette

Follow the instructions under Loading the Chemistry Protocol Diskette, earlier in this chapter, to load the user-defined reagent chemistry protocol templates.

Password Setup Procedure

Once a UDR chemistry has been defined and saved, the user must log in and perform a password setup procedure. This password protection feature is recommended for security purposes. The password setup is used to identify specific information, such as:

- who logged in
- which field was updated
- what screen was entered
- what field was changed

This and other information are described in the Display Events log. The password setup is described in the following steps.

Step	Action
1	Select the **Password Setup** box near upper right corner of the User-Defined Chemistries screen. Refer to Figure 5.6.
2	The User **Log in** screen appears. Refer to Figure 5.7. Note that the **Username** field defaults to ADMIN. Enter ADMIN in the Password field and select **<OK>**. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.
3	If **<OK>** was selected above, the UDR User Setup/Password Protection Mode screen appears. Refer to Figure 5.8. This screen is used to add or delete a user. Up to 16 users are allowed. Password protection is enabled by default (i.e., the Password Protection Mode box is checked.) If the Password Protection Mode box is disabled (not checked), the password protection feature is not available (i.e., no prompt after Define and Save.) To add another user, select a new user name number. Then select **<Define Edit User>** and proceed to Step 4.
4	A Define/Edit User screen appears. Refer to Figure 5.9. Enter a new user name in the **Username** field. Enter your password in the **Password** field. Enter the same password in the **Confirm Password** field.
5	To delete a user, select the username number and select **<Delete User>**. OR Select **<Cancel>** to return to the Password Protection Mode Screen.
6	Select **<Exit>** to return to the User Defined Chemistries screen.

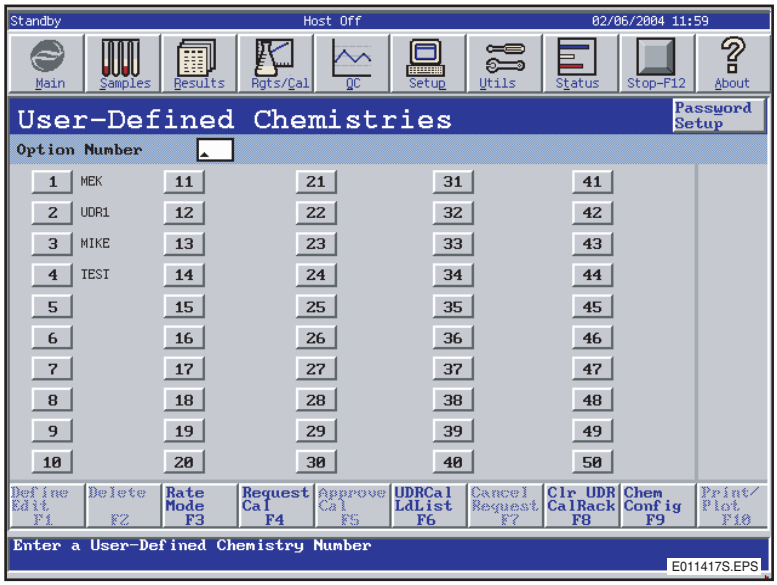


Figure 5.6 User-Defined Chemistries Screen

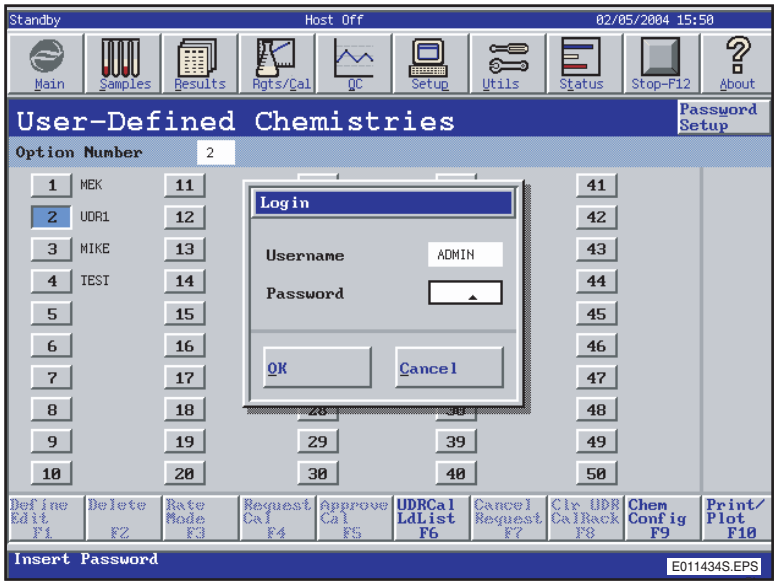


Figure 5.7 User Login Screen

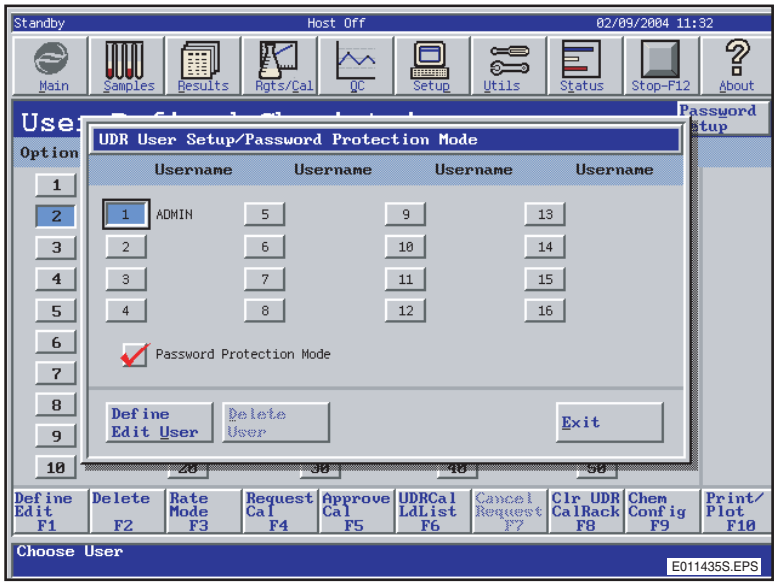


Figure 5.8 UDR User Setup/Password Protection Mode Screen

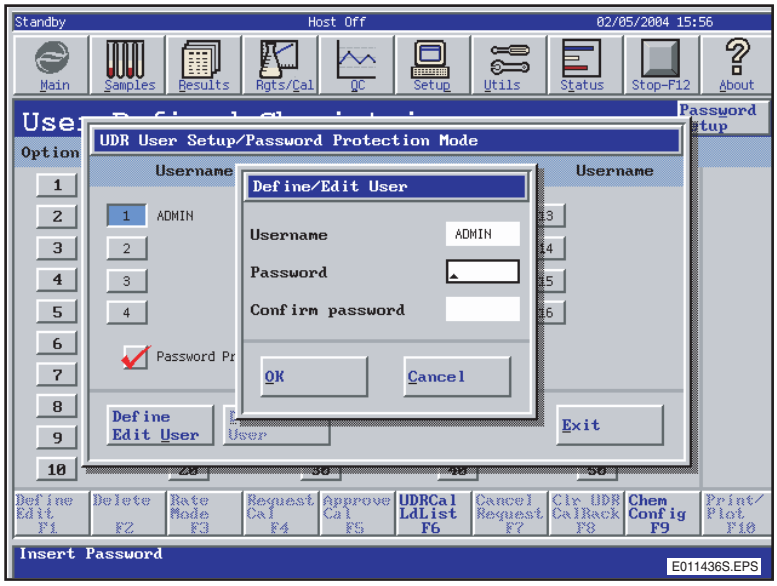


Figure 5.9 Define/Edit User Screen

Accessing Define/Edit

The instrument status must be in *Standby* in order to proceed with the steps below to access the Define/Edit screen.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	Select the UDR Option Number. (Refer to Figure 5.6.)
3	Select **Define/Edit [F1]**. (Refer to Figure 5.10 and Figure 5.11.) Continue to "Beginning a New UDR Protocol Definition" in this chapter.

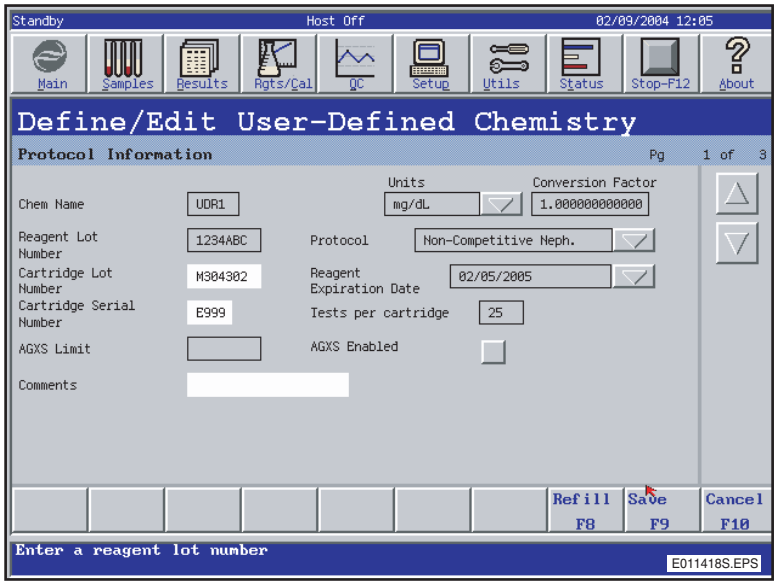


Figure 5.10 Define/Edit User-Defined Chemistry Screen, Page 1

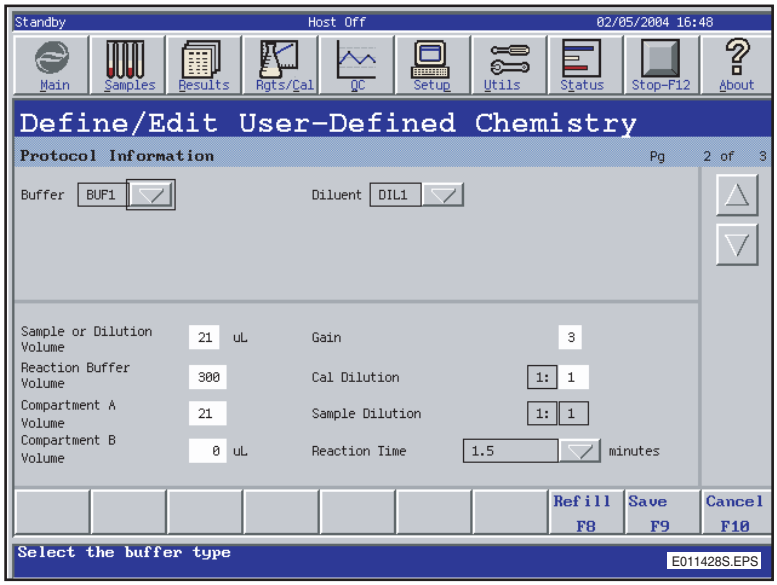


Figure 5.11 Define/Edit User-Defined Chemistry Screen, Page 2

Defining a UDR Chemistry

Description of Definition Fields

The following table describes the fields of the Define/Edit User-Defined Chemistry screen, Page 1. (Refer to Figure 5.10.) Use the tab key to navigate.

Table 5.1 Protocol Definition Fields, Page 1

Field	Entries Allowed	Function
Chem Name	Two to five alphanumeric characters	Unique name for chemistry.
Reagent Lot Number	A maximum of eight alphanumeric characters	Identifies reagent lot number.
Cartridge Lot Number	A maximum of eight alphanumeric characters	Identifies cartridge lot number.
Cartridge Serial Number	A maximum of four alphanumeric characters	Identifies unique serial number of UDR cartridge.
AGXS Limit	1-9999	Identifies Antigen Excess limit rate.
Comments	A maximum of 20 alphanumeric characters	Provides additional vendor information, or other comments.
Units	Selection from list	Concentration Units of UDR results.
Conversion Factor	Not applicable	• Displays the conversion factor input from the Units option button.
Protocol	Selection from list: • Non-Competitive nephelometric • Competitive nephelometric • Non-Competitive NIPIA • Competitive NIPIA	• Immunoprecipitin reaction detected by rate nephelometry. • Inhibition immunoprecipitin reaction detected by rate nephelometry. • Immunoprecipitin reaction detected by rate turbidimetry. • Inhibition immunoprecipitin reaction detected by rate turbidimetry.
Reagent Expiration Date	Date in order as defined in Date Setup	Reagent will be flagged on reports as expired after this date.

(1 of 2)

Table 5.1 Protocol Definition Fields, Page 1, continued

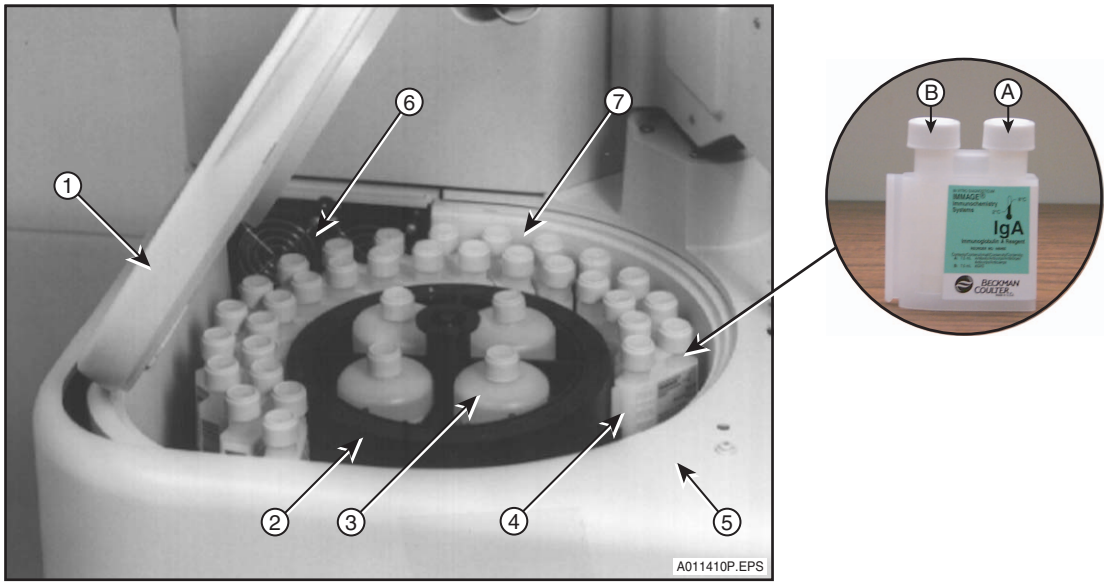
Field	Entries Allowed	Function
Tests per Cartridge	1-300	Identifies the number of tests available in the reagent cartridge.
AGXS Enabled	Select (check) to enable	Allows usage of AGXS Limit field.

(2 of 2)

The following table describes the protocol fields of the Define/Edit User-Defined Chemistry screen, Page 2. (Refer to Figure 5.11.)

Table 5.2 Protocol Definition Fields, Page 2

Field	Entries Allowed	Function
Buffer	BUF 1 to 4, or BUF 10 to 15	Identifies type of buffer used in test.
Diluent	DIL 1 to 4, or DIL 10 to 15	Identifies type of diluent used in test.
Sample or Dilution Volume	3 µL to 21 µL or 3 µL to 75 µL, depending on the sample dilution	Sample or dilution volume dispensed to reaction cuvette.
Reaction Buffer Volume	"0"; or from 195 µL to 300 µL	Reaction buffer volume dispensed.
Compartment A Volume (Refer to Figure 5.12.)	5 µL to 235 µL	Reagent volume aspirated from cartridge, compartment A.
Compartment B Volume (Refer to Figure 5.12.)	"0" ; or from 5 µL to 235 µL	Reagent volume aspirated from cartridge, compartment B.
Gain	1, 2, 3, 4	Signal amplification. As gain number increases, signal amplification increases.
Cal Dilution	1:1; or 1:5 to 1:50	Determines dilution ratio for calibration.
Sample Dilution	1:1; or 1:5 to 1:50	Determines dilution ratio for sample predilution.
Reaction Time	Select from list: 1.5 to 10 minutes	Interval in which reaction readings are taken after addition of the last reagent to the reaction mixture.



1. Reagent Compartment Cover
2. Reagent Carousel
3. Reaction Buffer Bottle
4. Reagent Cartridges (Compartments A and B)
5. Reagent Bar Code Reader
6. Fans
7. Temperature Sensor

Figure 5.12 The Reagent Compartment

The following table describes the calibration fields of the Define/Edit User-Defined Chemistry screen, Page 3. (Refer to Figure 5.13.)

Table 5.3 Calibration Definition Fields, Page 3

Field	Entries Allowed	Function
Levels	4 to 9	Identifies the number of calibrators used in test.
Replicates	1 to 9	Allows a number of tests to be repeated for each calibration level.
Update Level	1 to 9	Single-point calibration setpoint update level.
Replicates	1 to 9	Set point update replicate.
Cal Level Setpoints	Up to 6 digits with a decimal point, or seven digits.	Identifies concentration value for each calibration level in ascending order where Level 1 is the lowest concentration value.

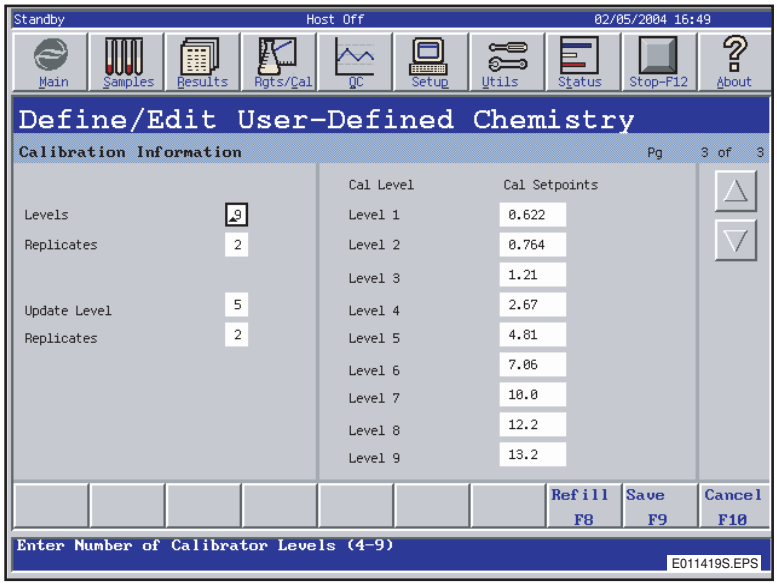


Figure 5.13 Define/Edit User-Defined Chemistry Screen, Page 3

Order of Reaction

The following table describes the order of reaction as determined by the type and volume of reaction components defined.

Table 5.4 Order of Reaction

If the Reaction Buffer Volume is…	and the Compartment B Volume is…	the Order of Reaction is…
Between 195-300 µL	0 µL	UDR buffer > Incubate > Neat or Diluted Sample > Compartment A Reagent starts reaction
Between 195-300 µL	Between 5-235 µL	UDR buffer > Compartment B Reagent > Incubate > Neat or Diluted Sample > Compartment A Reagent starts reaction
0 µL	Between 195-235 µL	Compartment B Reagent > Neat or Diluted Sample > Incubate > Compartment A Reagent starts reaction

Recommended Order for UDR AGXS Flagging Limit Use

Step	Action
1	Define UDR parameters
2	Perform UDR multi-point calibration.
3	Approve UDR multi-point calibration. Note: If calibration verification is desired, run the calibration verification BEFORE changing the sample dilution.
4	Change UDR sample dilution (optional).
5	Perform UDR AGXS Limit determination testing using UDR Rate Mode.
6	Enter UDR AGXS Limit (rate value) and select (check) the AGXS Enable box to begin UDR AGXS flagging. The AGXS Enable box is located in the Define/Edit User-Defined Chemistry screen (Refer to Figure 5.10).
7	Run UDR samples and perform single-point UDR calibration updates.

Additional Information

Refer to IMMAGE 800 Immunochemistry System *Operation Manual* CHAPTER 3, *Theory of Operations*, Principles of Methodologies for theory of operation information.

Beginning a New UDR Protocol Definition

The instrument status must be in Standby to proceed with the steps below. Refer to the Define/Edit User-Defined Chemistry screen shown in Figure 5.10.

Step	Action
1	From Page 1 of the Define/Edit User-Defined Chemistry screen, enter the UDR chemistry name in the **Chem Name** field. This field is limited to 2-5 alphanumeric characters. The chemistry name must not be in use for any other chemistry or calculation.
2	Select the options button **<▼>** beside the **Units** field.
3	Select the number for the desired unit.
4	Enter the reagent lot number in the **Reagent Lot Number** field.
5	Select the options button **<▼>** beside the **Protocol** field.
6	Select the number for the desired protocol.
7	Select the **Cartridge Lot Number** field.
8	Enter the cartridge lot number from the UDR cartridge. The lot number is found on the bar code label of the UDR cartridge supplied by Beckman Coulter.

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Step	**Action**, continued
9	Select the options button **<▼>** beside the **Reagent Expiration Date** field.
10	Enter the reagent expiration date. NOTICE The expiration date must not be the current date. Recalibration will be necessary when the expiration date is changed.
11	Select **<OK>** to enter the expiration date into system. OR Select **<Cancel>** to exit the dialog box without entering the date. Continue to "Defining UDR Sample/Reagent Volumes."
12	Enter the reagent cartridge serial number in the **Cartridge Serial Number** field. The serial number is found on the bar code label of the UDR cartridge supplied by Beckman Coulter.
13	Enter the number of tests in the **Tests per Cartridge** field. The maximum number of tests is 300.
14	If desired, select the **Comments** field and enter vendor information or other comments. This field is limited to 20 alphanumeric characters.

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Defining an AGXS Limit

The AGXS Limit is a user-defined value. The AGXS Limit feature will only be available if the UDR has a status of "calibrated" and uses a "Non-Competitive Nephelometric" or "Non-Competitive NIPIA" protocol. Entry of this value in the AGXS Limit field is only available after a UDR multi-point calibration has been performed and approved.

Entering an AGXS Limit value into the UDR definition will clear the calibration program of the defined UDR. The AGXS limit is calibration specific; therefore, recalibrating a UDR using a multi-point calibration will clear the AGXS Limit field and disable AGXS flagging.

During the sample run, if the calibrated rate for a UDR sample reaction is equal to or greater than the value entered for the AGXS Limit in the UDR definition, the system will suppress the results and display ******* in the results column on the results display and printout instead of a numerical result. AGXS flagging shall not apply during UDR Rate Mode runs.

Refer to follow the steps to enter an AGXS flagging rate value.

Step	Action
1	From the User-Defined Chemistries screen, select the chemistry for AGXS flagging. (Refer to Figure 5.6.)
2	Select **Define Edit**.
3	A user defined warning message appears. Read the message and select **<OK>**.
4	Select the **AGXS Enable** box.
5	Enter Rate Units into AGXS Limit field.
6	Select **Save [F9]**.
7	If your password is protected, then refer to the Password Setup Procedure in this chapter and enter your user name and password.
8	Select **<OK>**.

Defining UDR Sample/Reagent Volumes

The minimum total cuvette volume of reagent(s) and sample is 195 µL.

The maximum total cuvette volume of reagent(s) and sample is 365 µL.

The instrument status must be in *Standby* in order to proceed with the steps below to define UDR sample and reagent volumes. (Refer to Figure 5.11.)

Step	Action
1	From Page 2 of the Define/Edit User-Defined Chemistry screen, select the **Buffer** options button beside the Buffer field.
2	Select the buffer type from the list.
3	Select the **Diluent** options **<▼>** button beside the Diluent field.
4	Select the diluent type from the list.

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<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>5</td><td>Enter the volume of sample or sample dilution to be aspirated and dispensed in the Sample or Dilution Volume field.

<table>
<tr><th>If the Sample Dilution field entry is...</th><th>the Sample or Dilution Volume field may be...</th></tr>
<tr><td>1:5 to 1:50</td><td>3 µL to 75 µL</td></tr>
<tr><td>1:1 (undiluted)</td><td>3 µL to 21 µL</td></tr>
</table>

NOTICE
Aspiration of neat serum and/or plasma sample volumes greater than 15 µL may result in carryover and is not recommended.</td></tr>
<tr><td>6</td><td>Enter the reaction buffer volume to be aspirated and dispensed in the Reaction Buffer Volume field. Entries may be "0" or from 195 µL to 300 µL.</td></tr>
<tr><td>7</td><td>Enter the volume of reagent to be aspirated and dispensed from Compartment A in the Compartment A Volume field. Entries may be from 5 µL to 235 µL.</td></tr>
<tr><td>8</td><td>Enter the volume of reagent to be aspirated and dispensed from Compartment B in the Compartment B Volume field.

<table>
<tr><th>If the Reaction Buffer Volume field entry is...</th><th>the Compartment B Volume field entry may be...</th></tr>
<tr><td>0</td><td>195 µL to 235 µL</td></tr>
<tr><td>195 µL to 300 µL</td><td>0 or 5 µL to 235 µL</td></tr>
</table></td></tr>
<tr><td>9</td><td>Enter the gain in the Gain field. Entries may be 1, 2, 3, or 4. The gain increases as the number increases.</td></tr>
<tr><td>10</td><td>Enter the calibration dilution in the Cal Dilution field. Entries may be from 1:5 to 1:50.
OR
Enter 1:1 for an undiluted sample.

The Sample Dilution field automatically displays the same value as the Cal Dilution field. No input is allowed until after calibration and approval.</td></tr>
</table>

(2 of 3)

Step	**Action**, continued
11	After calibration and approval, if the desired sample dilution is different from the calibration dilution, enter the sample dilution in the **Sample Dilution** field. Entries may be from 1:5 to 1:50. OR Enter 1:1 for an undiluted sample.
12	Select the options button **<▼>** beside the **Reaction Time** field.
13	Select the reaction time number from the list.
14	Select the **<Page Down>** button to go to Page 2 of the Define/Edit User-Defined Chemistry screen.
15	Continue to "Defining UDR Calibration Information."

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Defining UDR Calibration Information

Defining UDR Calibration Information

The out-of-range low value for the protocol is the lowest non-zero calibrator setpoint concentration. The out-of-range high value for the protocol is the highest calibrator setpoint concentration.

The instrument status must be in *Standby* in order to proceed with the steps below to define the calibration information on Page 3 of the Define/Edit User-Defined Chemistry screen. Refer to Figure 5.13

Step	Action
1	From Page 3 of the Define/Edit User-Defined Chemistry screen, enter the number of Cal Setpoint levels in the **Levels** field. Entries may be from four to nine.
2	Enter the number of replicates to be run per Cal Setpoint level in the **Replicates** field. Entries may be from one to nine.
3	Enter a Cal Level number in the **Update Level** field for a single-point calibration update. Entries may be from one to nine.
4	Enter the number of replicates to be run for the Update Level in the **Replicates** field. Entries may be from one to nine.
5	Enter the concentration value in each of the **Cal Setpoint** fields. The concentration values must be in ascending order with Level 1 being the lowest concentration. Each field entry is limited to seven digits or six digits with a decimal point. NOTICE The number of calibration levels limits the type of curve-fit model applicable to the UDR. (Refer to Approving a Calibration, "Curve-Fit Model Descriptions", later in this chapter.)
6	Select **Save [F9]** to save the protocol and calibration information. OR Select **Cancel [F10]** to exit the screen without saving the protocol.
7	Go to the User-Defined Chemistries screen (Figure 5.6) and select **Chem Config [F9]** to configure the UDR chemistry. (Refer to Configuring the Chemistry Menu in this chapter.)
8	From the Chemistry Configuration screen, select **UDR Main [F9]** to return to the User-Defined Chemistries screens.

Deleting UDR Chemistries

Removing a UDR Chemistry from the Chemistry Menu

This function removes the UDR chemistry from the chemistry configuration menu, from any configured control, and from any configured panel.

Deleting a UDR Definition

The Delete function deletes a UDR definition only if the chemistry has been removed from the chemistry menu. When the UDR definition is deleted, the UDR reference intervals and all associated, non-archived patient results are deleted. Refer to IMMAGE 800 Immunochemistry System *Operation Manual* CHAPTER 10, *Utilities*, Backup/Restore.

The instrument status must be in *Standby* in order to proceed with the steps below to delete a UDR definition.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	Choose a number beside the chemistry to be deleted.
3	Select **Delete [F2]**. (Refer to Figure 5.14.)
4	Select **<OK>** to delete the chemistry. OR Select **<Cancel>** to return to the User-Defined Chemistries screen without deleting the chemistry.
5	Remove the reagent cartridge from the reagent carousel.

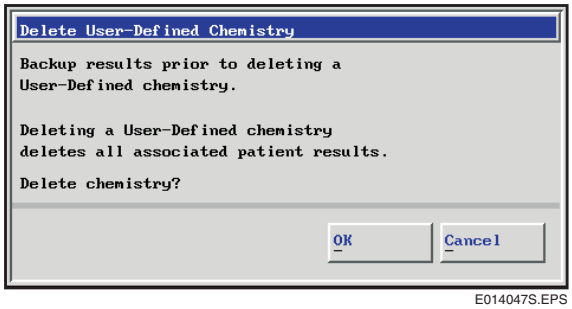

Figure 5.14 Delete User-Defined Chemistry Dialog Box

Editing UDR Definitions

Introduction

A previously defined UDR definition may be recalled and edited. Editing the sample dilution and/or AGXS Limit of a defined UDR clears the calibration programs for the UDR. Editing Comments, the Cartridge Serial Number and/or refilling a cartridge will not affect calibration. Editing anything else clears the calibration programs, cancels the calibration, clears the AGXS Limit, and disables AGXS flagging. The edited UDR definition is saved with the same chemistry name. Refer to Table 5.5 for further information.

Table 5.5 UDR Editing Function

Editing Function	Calibration Rack	Calibration Status	Curve-Fit Model
Clears calibration programs	Cleared	Calibrated	Cannot Change
Clears calibration programs and Cancels the calibration	Cleared	Uncalibrated	Cannot Change

Editing a UDR Definition

The units and chemistry name of the UDR cannot be changed unless the UDR is first removed from the chemistry menu.

The instrument status must be in *Standby* in order to proceed with the steps below to edit a UDR definition.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	Select a number beside a defined UDR position. (Refer to Figure 5.6.)
3	Select **Define/Edit [F1]**.
4	Refer to Defining a UDR Chemistry to edit the UDR definition and calibration information. NOTICE Editing the sample dilution or AGXS Limit of a defined UDR clears the calibration programs for that UDR. Editing Comments, Cartridge Serial and/or Refill numbers does not affect calibration. Editing anything else clears the calibration programs, cancels the calibration, clears the AGXS Limit and disables AGXS flagging. If the serial number is changed in the protocol definition, the cartridge identified by the overwritten serial number is no longer usable, regardless of the number of tests remaining.

Editing a UDR Definition is summarized in Table 5.6 below.

Table 5.6 Editing a UDR Definition

Edited UDR Definition	Effect on Calibration	Effect on AGXS Flagging
Comments Serial Number Refill Cartridge	No Effect Status: Calibrated	No Effect
Sample Dilution AGXS Limit	Clears Program Status: Calibrated	No Effect
All Other Parameters	Clears Program Cancels Calibration Status: Uncalibrated	Clears AGXS Limit Disable Flagging

Loading UDR Reagent Cartridges

Introduction

The UDR reagent cartridges must be loaded before performing a run.

Description of Cartridge

The UDR cartridge provided by Beckman Coulter contains the following information:

- Cartridge lot number
- Cartridge serial number.

Limits

- Six UDR cartridges may be loaded on the reagent carousel at one time.
- Each UDR cartridge has a set number of 300 tests. When the 300 tests count down to zero, a new UDR serial number and/or cartridge lot number must be defined and loaded.
- When the cartridge is level sensed as empty, but more tests are available on the Reagent/ Calibration Status screen, the UDR cartridge may be refilled and reused until the tests remaining is zero.

Loading UDR Cartridges

Follow the instructions in IMMAGE 800 Immunochemistry System *Operation Manual* CHAPTER 6, *Reagents/Calibration*, Loading/Unloading Reagent Cartridges, "Loading Reagent Cartridges."

Refilling UDR Cartridges

A UDR can be programmed to run a maximum of 300 tests. If the cartridge holds less than 300 tests, the cartridge may be refilled to reach the maximum 300 tests. Follow the steps below to refill the UDR cartridge.

Step	Action
1	Go to the **User-Defined Chemistry** screen. (Refer to Figure 5.6.)
2	Select a UDR.
3	Select **Define/Edit [F1]**.
4	Select **<OK>** to close the warning message.
5	Select **Refill [F8]** at the Defined/Edit-User Defined Chemistry screen. (Refer to Figure 5.10.)
6	Select the **Cartridge Serial Number** on the UDR Cartridge Refill screen. (Refer to Figure 5.15.)

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Step	Action, continued
7	Select **<Refill>**. The system will update tests remaining in the cartridge to the number of tests defined in the Defined/Edit-User Defined Chemistry screen. OR Select **<Exit>** to return to the Defined/Edit-User Defined Chemistry screen without refilling the cartridge.
8	Refill the cartridge.

(2 of 2)

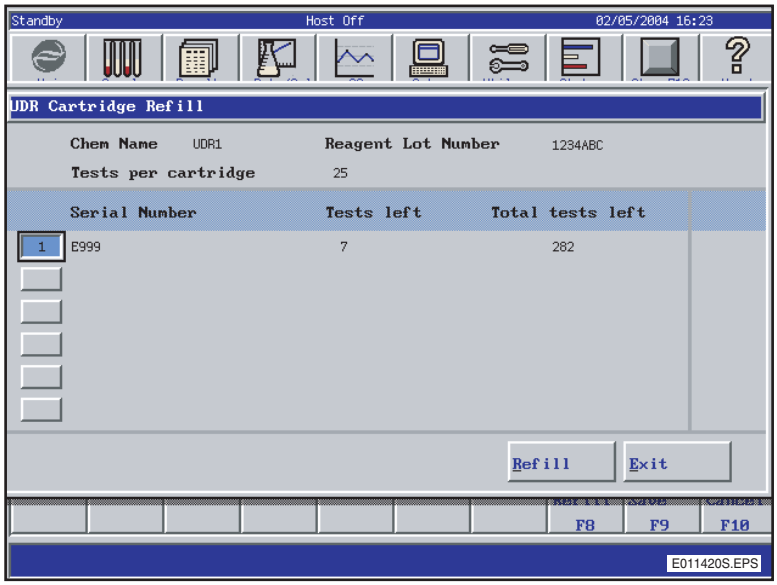


Figure 5.15 UDR Cartridge Refill Screen

The UDR Cartridge Refill screen (Figure 5.15) is defined in Table 5.7:

Table 5.7 UDR Cartridge Refill Screen

Screen Item	Screen Definition
Chem Name	Chemistry Name as defined in Figure 5.10.
Reagent Lot Number	Reagent Lot Number as defined in Figure 5.10.
Tests per cartridge	Tests per cartridge as defined in Figure 5.10.
Serial Number	Cartridge Serial number as defined in Figure 5.10
Tests left	Number of tests remaining from tests per cartridge defined in Figure 5.10.
Total tests left	Number of tests remaining from 300 total tests per cartridge.

Removing UDR Cartridges

Follow the instructions in IMMAGE 800 Immunochemistry *Operations Manual*, CHAPTER 6, *Reagents/Calibration*, Loading/Unloading Reagent Cartridges, "Removing Cartridges from The Reagent Carousel."

Loading/Clearing UDR Buffer and Diluent

Introduction

Beckman Coulter IMMAGE 800 buffers and diluents, or user-prepared solutions, may be used as UDR buffer and diluent. However, the UDR buffer and diluent are given a specific name on the sample or reagent carousel. The positions and lot numbers of UDR buffer and diluent must be entered into the computer.

- Up to 4 bottles of UDR buffers may be placed on the inner section of the reagent carousel.
- Up to 4 bottles of UDR sample diluents may be placed on the inner section of the sample carousel.

Checking UDR Buffer/Diluent Status

The instrument status must be in *Standby* in order to proceed with the steps below to check the buffer and diluent status before a run.

Step	Action
1	Select **Reagents/Cal** from the menu bar.
2	Select **Buffer/Diluent [F3]**. (Refer to Figure 5.16.)
3	Check the **% Remaining** for a sufficient amount to complete a run. • The designation for a UDR buffer is BUF1-4 and BUF 10-15. BUF 1-4 is designated for system buffer. BUF 10-15 is designated for user-defined buffer. • The designation for a UDR diluent is DIL1-4 and DIL 10-15. DIL 1-4 is designated for system diluent. DIL 10-15 is designated for user-defined diluent.

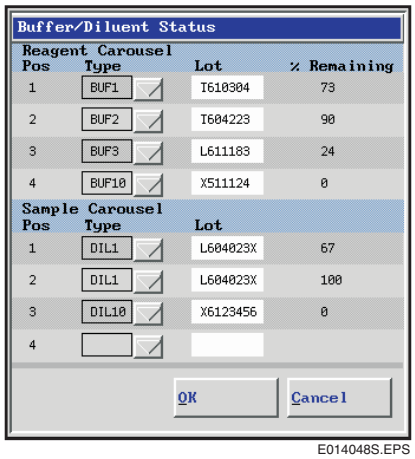


Figure 5.16 Buffer/Diluent Status Dialog Box

Loading a New Lot of UDR Buffer/Diluent or Changing a Position

Follow the instructions in IMMAGE 800 Immunochemistry *Operations Manual*, CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, "Loading A New Lot Or Changing A Position."

Replacing the Same Lot of UDR Buffer/Diluent

Follow the instructions in IMMAGE 800 Immunochemistry *Operations Manual*, CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, "Replacing the Same Lot."

After Loading Buffers and Diluents

NOTICE
Recalibration of affected reagents may be necessary when buffer or diluent lot numbers are changed.

The system assumes that lot numbers and position numbers for buffers or diluents remain the same from run to run until changed by the user.

The **% Remaining** volume on the Buffer/Diluent Status dialog box is updated during a sample run.

Clearing a UDR Buffer/Diluent Position

Refer to IMMAGE 800 Immunochemistry *Operations Manual*, CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, "Clearing a Buffer or Diluent Position."

Programming Rate Mode

Introduction

After the UDR chemistry protocol is defined and the chemistry is configured, Rate Mode is used to optimize UDR parameters. After running the UDR chemistry, a report with only instrument responses (IR) is automatically generated. A maximum of six UDRs may be programmed at one time in rate mode. Rate Mode can be run on a calibrated or uncalibrated UDR.

Programming Rate Mode

The instrument status must be in *Standby* in order to proceed with the steps below to program a UDR for rate mode.

Step	Action
1	From the User-Defined Chemistry screen, select **Rate Mode [F3]**. (Refer to Figure 5.17.)
2	Select up to six of the UDR chemistries.
3	Select **<OK>** to continue. Rate Mode may be run on a calibrated or uncalibrated UDR. NOTICE Rate results are always uncalibrated rate, whether the UDR is calibrated or uncalibrated. OR Select **<Cancel>** to exit rate mode and return to the User-Defined Chemistry screen.
4	From the UDR Rate Mode Assign screen (Refer to Figure 5.18.), enter an *available* rack number in the **Rack** field. OR Select **Clear Racks [F1]** and Enter the racks and/or positions to clear. Select **<OK>** to clear or **<Cancel>** to exit without clearing.
5	Enter a position number in the **Pos** field. Up to nine positions may be entered.
6	Enter a Sample ID in the **Sample ID** field for each position assigned. Up to 15 characters may be entered.
7	Select **Save [F9]** to save the program. OR Select **Cancel [F10]** to exit the screen without saving the program.
8	Repeat Steps 1-7 to program additional racks for rate mode.
9	Print a Load List from Sample Programming.

(1 of 2)

Step	**Action**, continued
10	Load the samples on the sample carousel.
11	Select **Main** from the menu bar and **Run**.
12	Select **<OK>** in the Check Dilution Segments dialog box to start the run. OR Select **<Cancel>** to exit without starting the run.

(2 of 2)

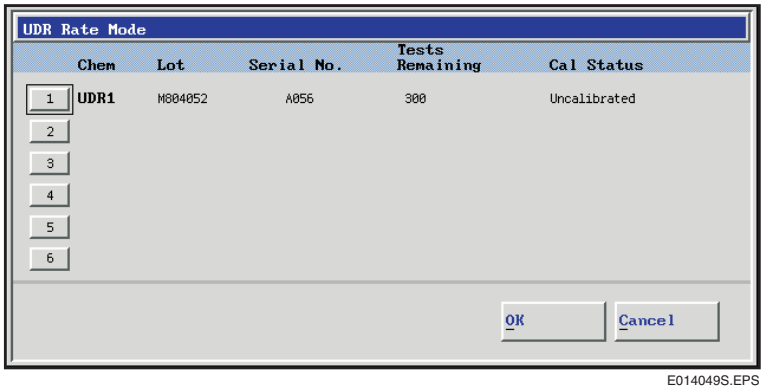


Figure 5.17 UDR Rate Mode Dialog Box

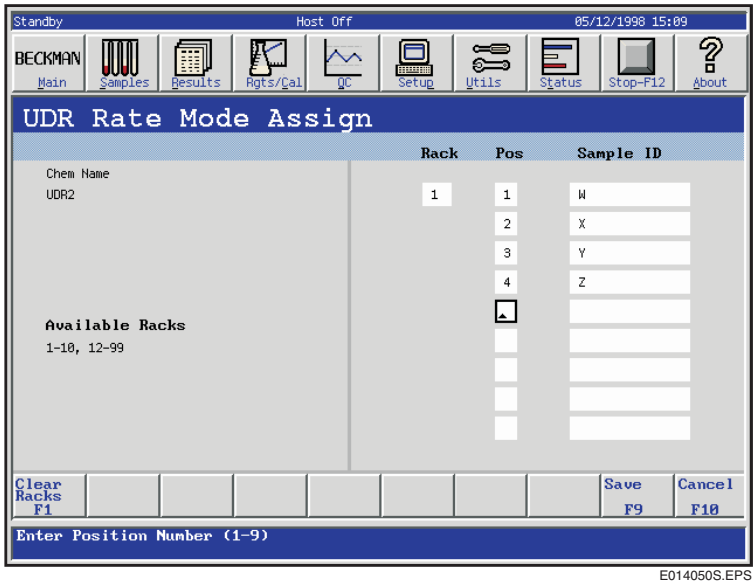


Figure 5.18 UDR Rate Mode Assign Screen

Additional Information

Refer to IMMAGE 800 Immunochemistry *Operations Manual*, CHAPTER 7, *Preparing for Programming/Running*, Clearing a Sample and Requesting a Load List.

Refer to IMMAGE 800 Immunochemistry *Operations Manual*, CHAPTER 8, *Results Recall*, Printing Recalled Results to reprint UDR rate mode results.

Refer to IMMAGE 800 Immunochemistry *Operations Manual*, APPENDIX C, *Reports* for an example of a Rate Mode report.

Calibrating a UDR Chemistry

Introduction

A UDR can be calibrated by using a multi-point calibration. Subsequently, this calibration may be updated using a single-point update calibration. The UDR chemistry calibration, using a multi-point calibration or single-point update, requires that the protocol definition be completed and the chemistry name configured. The calibration is programmed from the User-Defined Chemistries screen shown in Figure 5.6. The calibrators are run as routine test samples using the defined protocol. A UDR calibration must be on a separate run from samples for that UDR chemistry. The instrument response (IR) for each calibrator replicate is generated.

Once the calibration is approved, the UDR cal status is in *Calibrated* and UDR chemistries can be run with other Beckman Coulter chemistries. Using the UDR calibration data, the system will calculate a final result in the concentration units selected in the protocol.

Programming a UDR Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to program a UDR calibration.

Step	Action
1	From the User-Defined Chemistries screen, select **Request Cal [F4]**. The UDR chemistries on the reagent carousel will be displayed. (Refer to Figure 5.19.)
2	Select up to six UDR chemistries for calibration.
3	Select **<OK>** to continue. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.
4	From the UDR Cal Assign screen, enter an *available* rack number in the **Rack** field. (Refer to Figure 5.20.) OR Select **Clear Racks [F1]** and enter the racks and/or positions to clear. Select **<OK>** to clear or **<Cancel>** to exit without clearing.
5	After a rack number is entered, the position numbers will automatically fill in the **Pos** field according to the levels defined for the chemistry displayed. The calibrators must be programmed in ascending concentration, with Level 1 being the lowest concentration.
6	Enter a Cal ID in the **Cal ID** field (optional). Up to 18 characters may be entered.

(1 of 2)

Step	Action, continued
7	Select **Save [F9]** or a menu bar icon to save the calibration program for the displayed chemistry. OR Select **Cancel [F10]** to exit the screen without saving any calibration programs.
8	Repeat Steps 4-7 to program additional racks for calibration of other UDR chemistries.

(2 of 2)

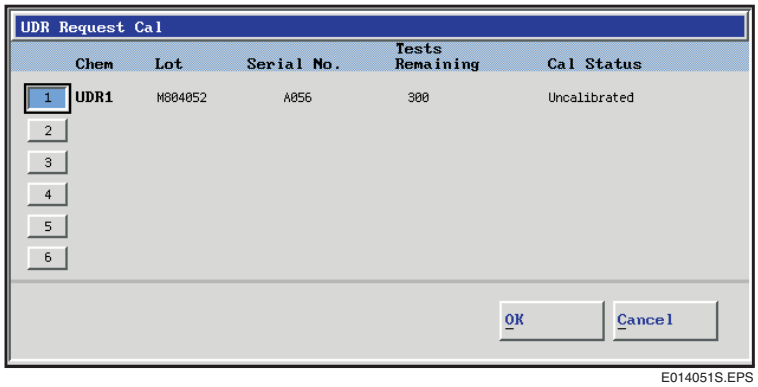


Figure 5.19 UDR Request Cal Dialog Box

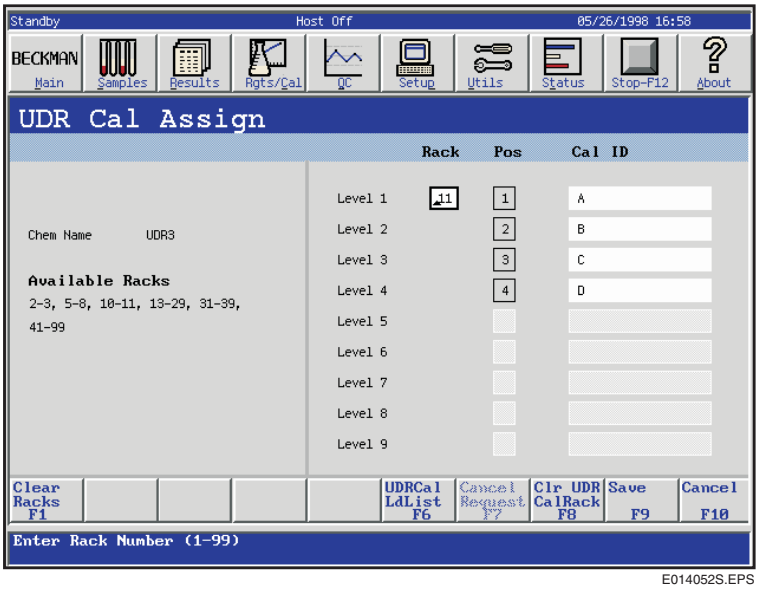


Figure 5.20 UDR Multi-point Cal Assign Screen

Programming a Single-Point UDR Calibration

A single-point calibration update can be performed on a UDR after a multi-point calibration has been performed and approved. This option is not available prior to multi-point calibration. The single-point calibration update result is compared to the multi-point calibration and the system calculates a scale factor. After the update is approved, the scale factor is applied to quality control results and patient results.

The instrument status must be in *Standby* in order to program a single-point UDR calibration. Program a single-point calibration as follows:

Step	Action
1	From the User-Defined Chemistries screen, select **Request Cal [F4]**. (Refer to Figure 5.6.) The UDR chemistries on the reagent carousel will be displayed.
2	Select up to six UDR chemistries for calibration.
3	Select **<OK>** to continue. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.
4	From the UDR Cal Assign screen, select (check) the single-point update box. The predefined update single-point level and the **Cal ID** fields will be enabled. (Refer to Figure 5.21.)
5	From the UDR Cal Assign screen, enter an *available* rack number in the **Rack** field. OR Select **Clear Racks [F1]** and enter the racks and/or positions to clear. Select **<OK>** to clear or **<Cancel>** to exit without clearing.
6	After a rack number is entered, fill in the **Pos** field according to the level defined for the chemistry displayed.
7	Enter a Cal ID in the **Cal ID** field (optional). Up to 18 characters may be entered.
8	Select **Save [F9]** or a menu bar icon to save the calibration program for the displayed chemistry. OR Select **Cancel [F10]** to exit the screen without saving any calibration programs.
9	Repeat Steps 1-7 to program additional racks for calibration of other UDR chemistries.

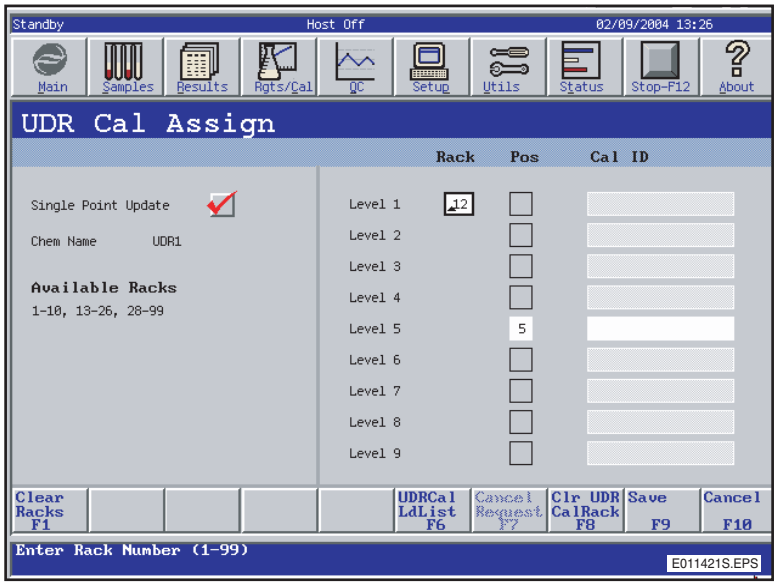


Figure 5.21 UDR Cal Assign Screen

Requesting a UDR Cal Load List

The instrument status must be in *Standby* in order to proceed with the steps below to request a UDR load list.

Step	Action
1	From either the User-Defined Chemistries screen or the UDR Cal Assign screen, select **UDRCal LdList [F6]**. (Refer to Figure 5.22.)
2	Select **Print [F10]** to print the load list or **UDRCal [F9]** to return to the UDR Cal screen. (Refer to IMMAGE 800 Immunochemistry System *Operations Manual*, APPENDIX C, *Reports* for an example of a Calibration Load List.)

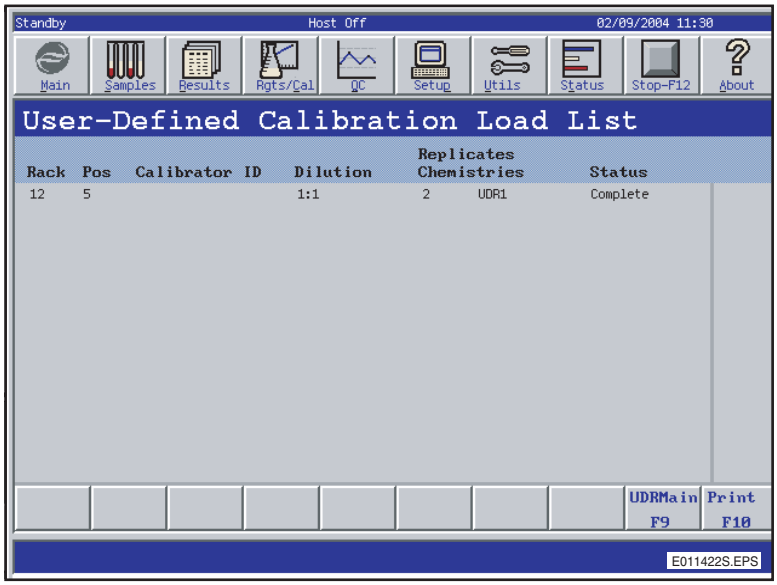


Figure 5.22 User-Defined Calibration Load List Screen

Running the UDR Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to run a UDR calibration.

Step	Action
1	Load the calibration samples in the appropriate racks.
2	Select **Main** from the menu bar and **Run**.
3	Select **<OK>** in the Check Dilution Segments dialog box to start the run. OR Select **<Cancel>** to exit without starting the run.
4	When the calibration run is finished, a multi-point or single-point UDR Calibration Results report is printed. Continue to "Approving a UDR Calibration."

Canceling a UDR Cal Request

The instrument status must be in *Standby* in order to proceed with the steps below to cancel a UDR cal request.

Step	Action
1	From either the User-Defined Chemistries screen or the UDR Cal Assign screen, select **Cancel Request [F7]**. (Refer to Figure 5.23.)
2	Select the requested chemistries to be canceled.
3	Select **<OK>** to cancel the calibration request. The Cal Status of the canceled chemistries will return to the status prior to the calibration request. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.

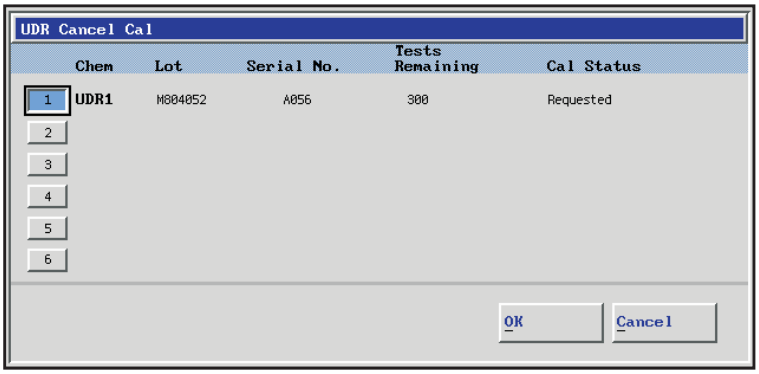


Figure 5.23 UDR Cancel Cal Dialog Box

Clearing a UDR Cal Rack

The instrument status must be in *Standby* in order to proceed with the steps below to clear a UDR Cal rack.

NOTICE

Do not clear a UDR Cal rack until the final curve-fit model for the calibration has been selected.

Step	Action
1	From either the User-Defined Chemistries screen or the UDR Cal Assign screen, select **Clear UDR Cal Rack [F8]**. (Refer to Figure 5.24.)
2	Enter the racks to clear in the **Rack(s)** field.
3	Select **<OK>** to clear the rack. OR Select **<Cancel>** to exit without clearing. NOTICE Clearing the User-Defined Calibration Rack will clear the rack positions. The calibration results for this rack will be deleted. After clearing the rack, the calibration results cannot be displayed with the current model, with a different model, or be printed.

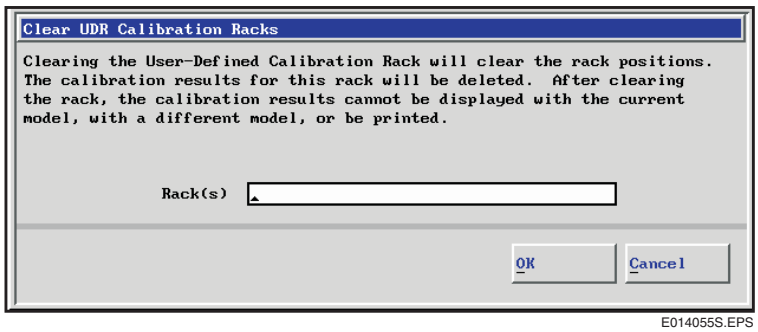


Figure 5.24 Clear UDR Calibration Racks Dialog Box

Approving a Calibration

Introduction

After the calibration run, the instrument response (IR) for each calibrator replicate is generated. The IR versus calibrator set point concentration, as well as curve-fit, is displayed as a plot using various curve-fit models. The calibration model can be selected for the UDR. The model and associated calibration parameters are saved for the reagent lot numbers defined for this UDR, or until another calibration is requested.

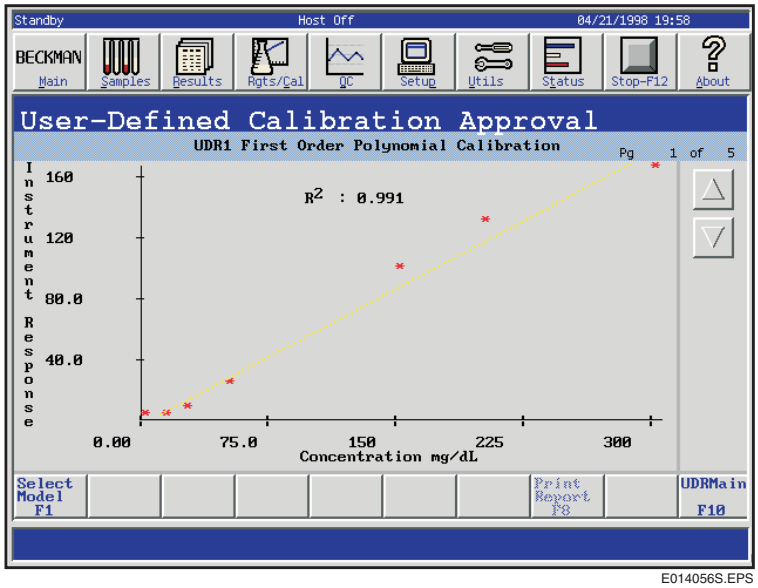
The four models available are First Order Polynomial, Second Order Polynomial, Third Order Polynomial, and Four Parameter Logistic.

Curve-Fit Model Descriptions

The following table describes the four curve-fit models. Refer to Figure 5.25 to Figure 5.31.

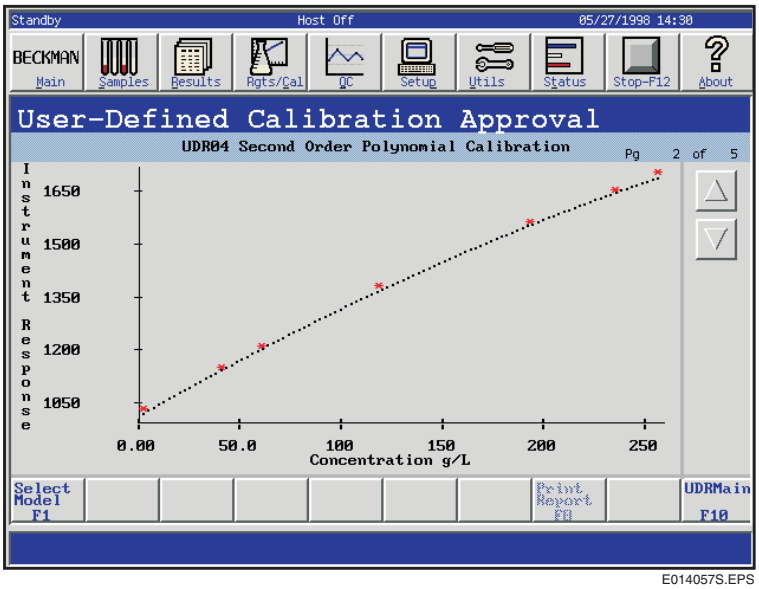
Table 5.8 Curve-fit Models

Model	Minimum number of calibrator levels to plot graph	Formula	Parameter Displayed
First Order Polynomial	4	$y = A + Bx$ A011363L.EPS	A B
Second Order Polynomial	5	$y = A + Bx + Cx^2$ A011364L.EPS	A B C
Third Order Polynomial	6	$y = A + Bx + Cx^2 + Dx^3$ A011365L.EPS	A B C D
Four Parameter Logistic	6	$y = \frac{A - D}{1 + \left[\frac{x}{C}\right]^B} + D$ A011366L.EPS	A B C D



E014056S.EPS

Figure 5.25 Example of First Order Polynomial Calibration



E014057S.EPS

Figure 5.26 Example of Second Order Polynomial Calibration

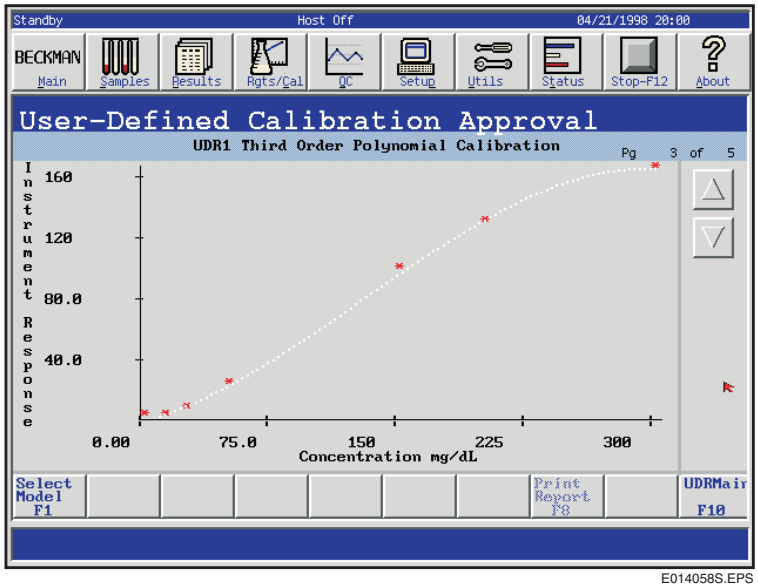


Figure 5.27 Example of Third Order Polynomial Calibration

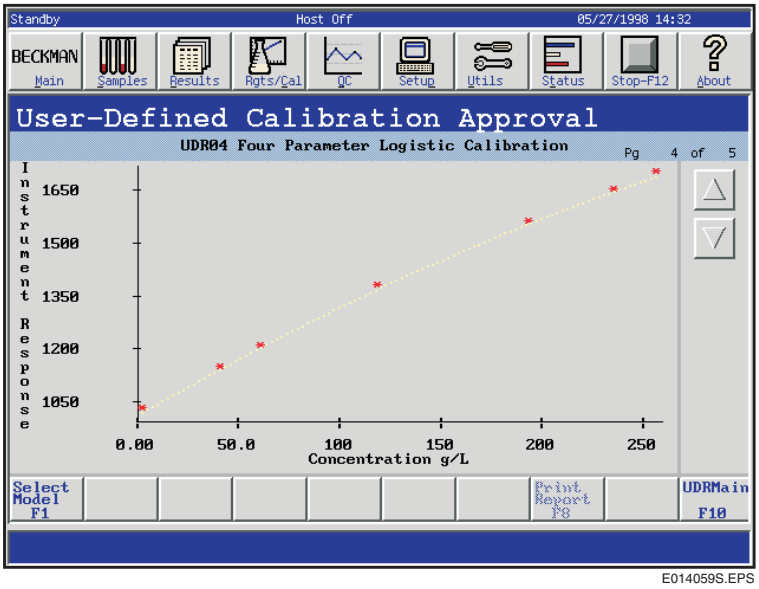


Figure 5.28 Example of Four Parameter Logistic Calibration

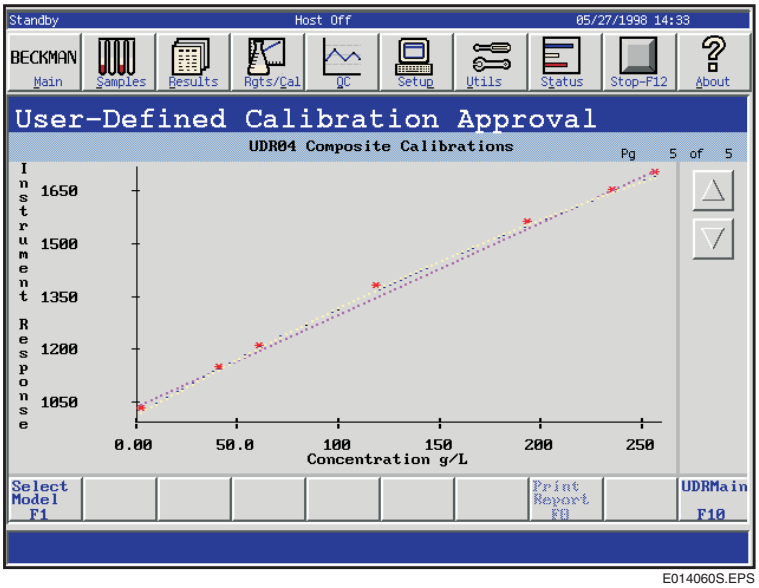


Figure 5.29 Example of Composite Calibration

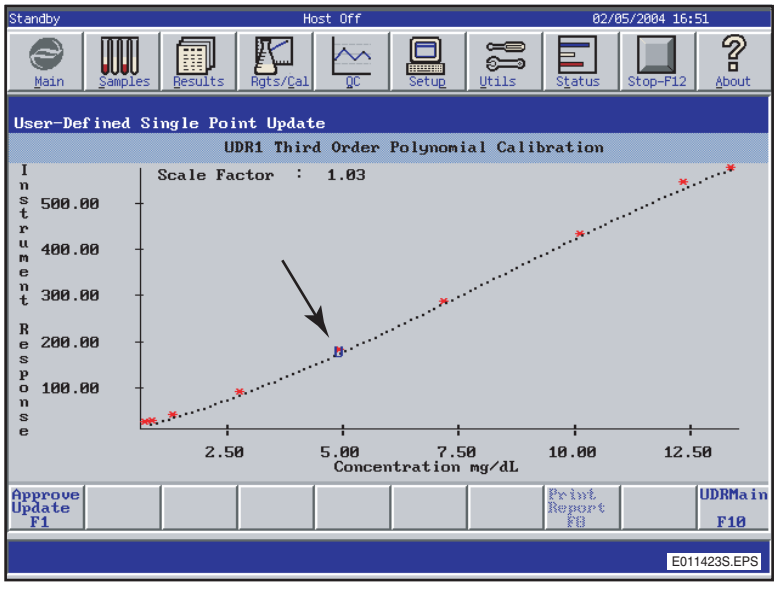


Figure 5.30 User-Defined Single-Point Update Screen

Plot Descriptions

The following table describes the plots.

Table 5.9 Plot Descriptions

Part	Description
X-axis	Calibrator setpoint concentrations and units defined by the protocol.
Y-axis	Instrument responses (IR) for each calibrator replicate.
Asterisks (*)	Each calibration data point.
Dotted line (.)	Calibration curve.
Letter U	Single-point update level.

Approving a UDR Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to approve a UDR calibration model.

The Multi-Point UDR Calibration Result report must show at least one instrument response (IR) for each calibrator level. If not, the entire calibration run must be repeated. The exception to rerunning the entire calibration occurs when one of the calibrator levels has a status of *Incomplete*. The incomplete sample may be rerun as part of the same calibration rack and its results added to the rest of the calibration data.

Step	Action
1	From the User-Defined Chemistries screen, select **Approve Cal [F5]**.
2	Use **<Page Up>** or **<Page Down>** to review the plots of the models for the calibration. The last page has a composite plot of all the models.
3	To print a curve-fit model plot, press **[Ctrl, P]** on the keyboard.
4	Select **Model [F1]** to display the curve-fit model options. (Refer to Figure 5.31.)
5	Select the number beside the model desired and select **<OK>** to approve the UDR calibration. OR Select **<Cancel>** to exit the User-Defined Model dialog box.
6	Select **Print Report [F8]** to print the data and statistics for a curve-fit model.
7	Program controls on the UDR through Sample Programming to see if they are acceptable with the chosen calibration model before clearing the UDR cal rack. To test another model with controls, repeat Steps 1-7.
8	When the final calibration model has been selected, clear the UDR calibration rack. Refer to "Clearing a UDR Cal Rack" in this chapter.

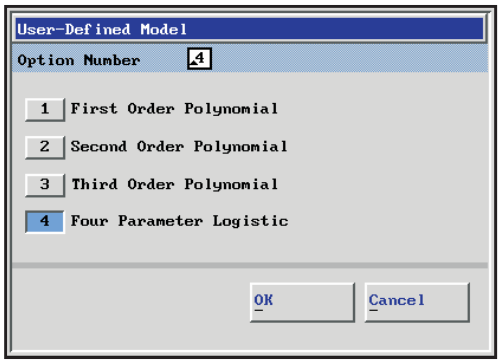


Figure 5.31 User-Defined Model Dialog Box

Approving a Single-Point UDR Calibration

The instrument status must be in *Standby* to proceed with the steps below to approve a UDR calibration model.

The single-point UDR Calibration Result report must show at least one instrument response (IR) for the single-point calibrator level. If not, a calibration run must be repeated.

Step	Action
1	From the User-Defined Chemistries screen (Figure 5.6), select the UDR chemistry and **Approve Cal [F5]**. NOTICE If a single-point calibration is approved with a scale factor that is not within the range (0.6667 - 2.0), the sample run will produce no concentration results. In this case, first rerun the single-point calibration. If the results are the same, run a multi-point calibration. Target instrument response +/- 50% for calibration update level.
2	Select **Approve Update [F1]** to approve the scale factor. (Refer to Figure 5.30). The only curve-fit model available is the approved multi-point calibrated curve-fit model. Note: The letter 'U' appears on the plot at the update level. A scale factor is also displayed on the plot window. (Refer to Figure 5.30.) NOTICE After programming and saving, a single-point calibration request, the curve-fit model cannot be changed. Each single-point calibration can only use the model from the last approved mult-point calibration. If the update level (letter U) does not appear on the plot window, the single-point calibration is not reliable. Repeat the single-point calibration. If the results are the same, perform a multi-point calibration.

(1 of 2)

Step	Action
3	To print a curve-fit model plot, press **[Ctrl, P]** on the keyboard.
4	Select **Print Report [F8]** to print the data and statistics for a curve-fit model.
5	Select **UDR Main [F10]** to return to the User-Defined Chemistries screen.
6	Program controls on the UDR through Sample Programming to see if the single-point calibration is acceptable. Another model cannot be tested.
7	When the calibration model has been approved, clear the UDR calibration rack. Refer to "Clearing a UDR Cal Rack" in this chapter.

(2 of 2)

Plotting a Robust Means Data Curve

The Robust Means Data Curve plots a Robust Means/Time curve for reagent development purposes. A Robust Means Data Curve may be plotted for UDR rate and calibration runs only. For further details, refer to Programming Rate Mode and Calibrating a UDR Chemistry in this chapter. Refer to the following steps to plot a Robust Means Data Curve.

Step	Action
1	Go to the User-Defined Chemistries screen and select a UDR chemistry. (Refer to Figure 5.6.)
2	Select **Print Plot (F10)**. A User-Defined Reports screen appears. (Refer to Figure 5.32.)
3	From the User Defined Reports screen, select option **<6> Plot Robust Means Data Curve** and **<OK>**. The Plot Robust Means Data Curve window appears as shown in Figure 5.33. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.
4	From the Plot Robust Means Data Curve window, enter the rack number, position number, and replicate number. Select **Plot** to plot the curve. A typical Robust Means Data Curve is shown in Figure 5.34. OR Select **<Exit>** to return to the previous screen.

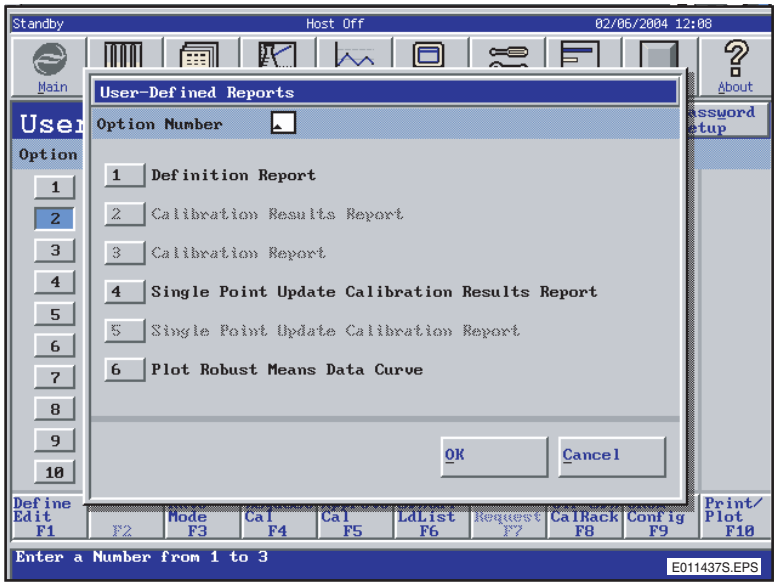


Figure 5.32 User-Defined Reports Screen

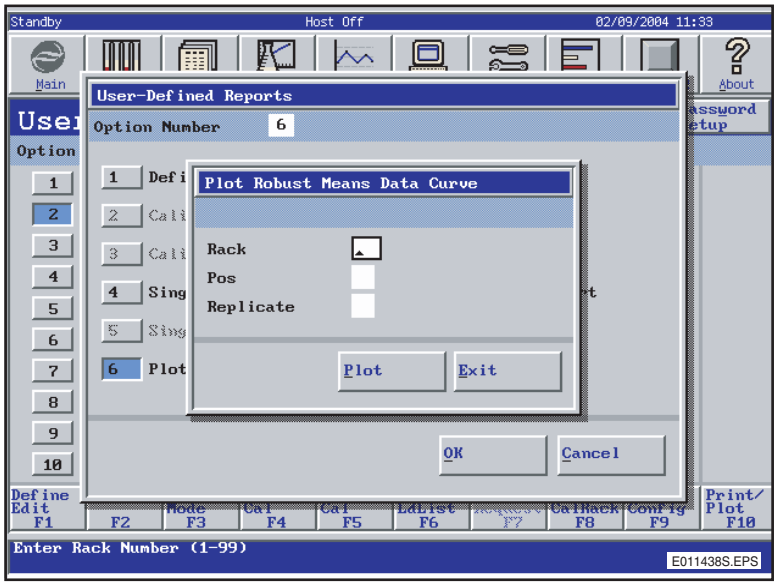


Figure 5.33 Plot Robust Means Data Curve Window

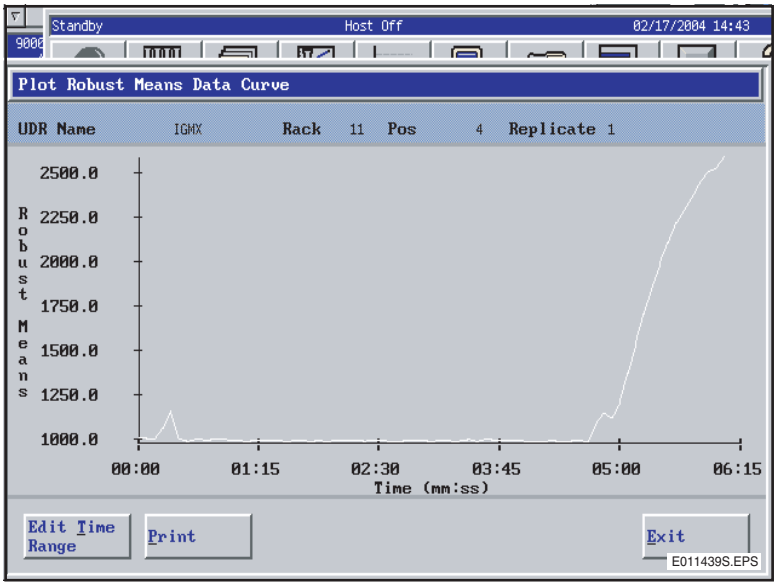


Figure 5.34 Plot Robust Means Data Curve

Editing the Time Range on a Robust Means Data Curve

The time range can be edited on a Robust Means Data curve in order to focus on a particular area of the curve. Perform the following steps to edit the time range.

Step	Action
1	Refer to Figure 5.34 and select **Edit Time Range** on the Robust Means Data Curve. A Time Range window appears as shown on Figure 5.35.
2	Enter the new starting time and ending time in the Time Range window. The new starting/ending times must be within the original time range as shown on the initial data curve.
3	A new Time Range screen appears that shows the edited times. Select **<OK>** to plot the new curve, and proceed to Step 4. OR Select **Default** to return to the original curve and time range. OR Select **<Cancel>** to return to the previous screen.
4	Select **<Exit>** to return to the Plot Robust Means Data Curve screen (Figure 5.33). OR Select **<Edit Time Range>** again and repeat this procedure. OR Select **<Print>** to print the the Plot Robust Means Data Report. OR Select **[Ctrl, P]** on the keyboard to print the Plot Robust Means Data Curve.

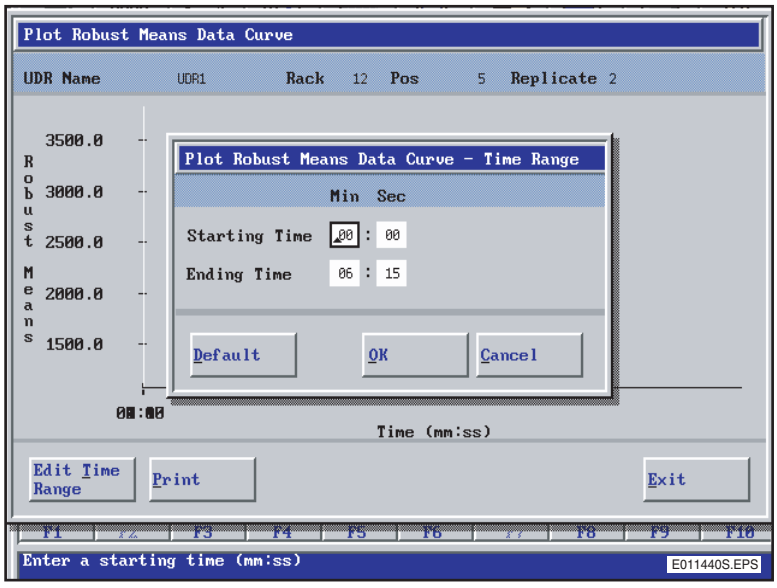


Figure 5.35 Plot Robust Means Data Curve - Time Range Window

Printing UDR Reports

Description of UDR Reports

The following table describes the UDR report options. Refer to IMMAGE 800 Immunochemistry System *Operations Manual*, APPENDIX C, *Reports*, for examples of the UDR Reports.

Table 5.10 UDR Reports

Report	Description
Definition Report	Identifies UDR chemistry definition protocol and calibration information.
Calibration Results Report	Identifies UDR instrument response results per replicate of each UDR calibrator for the selected chemistry.
Calibration Report	Identifies UDR mean instrument responses per replicate of each UDR calibrator for the selected chemistry, the curve-fit model, and associated parameters.
Single-Point Update Calibration Results Report	Identifies UDR instrument response results per replicate of single-point update calibrator for the selected chemistry.
Single-Point Update Calibration Report	Identifies UDR mean instrument responses per replicate of single-point update calibrator for the selected chemistry, the curve-fit model, associated parameters, and scale factor.
Plot Robust Means Data Report	Identifies UDR robust means data for a single replicate of a selected UDR calibrator or rate mode report.
Rate Mode Results	Identifies UDR instrument responses per replicate of each UDR sample for the selected chemistry.
Patient Results	Identifies UDR concentrations per replicate of patient sample programmed.

Printing UDR Reports

The instrument status must be in *Standby* in order to proceed with the steps below to print UDR reports.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	From the User-Defined Chemistries screen, choose one of the defined UDR positions.
3	Select **Print/Plot [F10]** to display the report options.
4	Select the number beside the report desired.
5	Select **<OK>** to print the report. OR Select **<Cancel>** to return to the User-Defined Chemistry screen.

Printing UDR Rate Mode and Patient Results

Follow the instructions in IMMAGE 800 Immunochemistry System *Operations Manual* CHAPTER 8, *Results Recall*, Printing Recalled Results to reprint UDR rate mode and patient results.

Setting Up UDR Reference Intervals and Panels

UDR Reference Interval and Panel Setup

UDR reference intervals and panels are defined like other Beckman Coulter chemistries from the Reference Interval Setup and Panel Setup screens. (Refer to IMMAGE 800 Immunochemistry System *Operation Manual* CHAPTER 5, *System Setup*, Reference Interval Setup, "Defining/Editing Intervals and Ranges" and Panel Setup, "Defining New Panels".)

Defining UDR Quality Control

UDR Quality Control Definition

UDR quality controls are defined like other Beckman Coulter chemistries from the Quality Control screen. (Refer to IMMAGE 800 Immunochemistry System *Operations Manual* CHAPTER 9, *Quality Control*, Defining a Control.)

Programming a UDR Sample

UDR Programming Reference

The UDR chemistry is programmed like an other Beckman Coulter chemistry from the Program Sample screen except that AGXS check cannot be chosen. (Refer to IMMAGE 800 Immunochemistry System *Operations Manual* CHAPTER 7, *Preparing for Programming/ Running*.)

Instrument Setup

Overview

Introduction

Some parts of the instrument hardware require a one-time setup prior to a sample run.

This section explains:

- Rack bar code label placement
- Wash solution box placement
- Waste container placement

Placing Labels on a Rack

Introduction

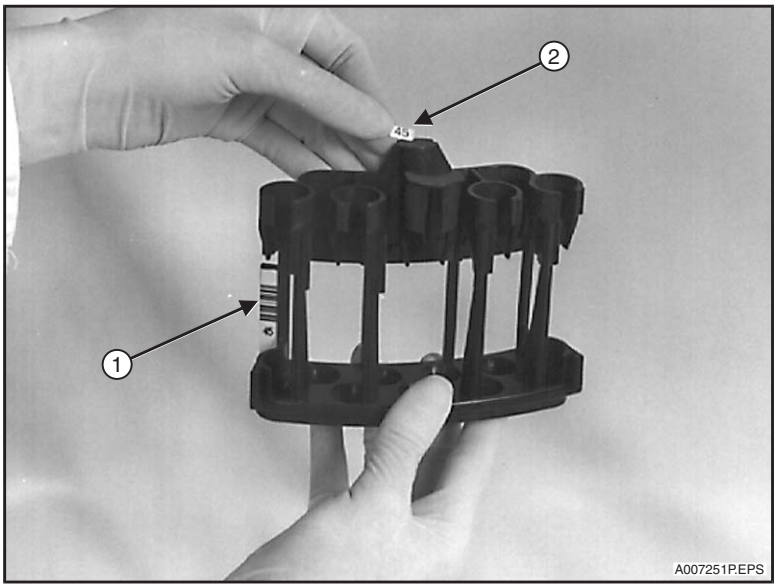
Two labels must be placed on each rack. The labels identify the rack number. One label is bar coded, the other label is a numbered label.

Placing the Bar Coded Label on the Rack

Place the bar coded rack label on the side of the rack as pictured in Figure 5.36.

Placing the Rack Number Label on the Rack

Place the rack number label on the top of the rack as pictured in Figure 5.36.



1. Rack bar code label
2. Rack number label

Figure 5.36 Rack Bar Code Label and Rack Number Label Placement

Wash Solution Box and Waste Container Placement

Wash Solution Box Placement

The wash solution box must be placed close enough to the instrument to allow connection of the wash solution tube.

Waste Container Placement

The waste container must be placed with the opening of the waste container no higher than the top of the instrument.

CHAPTER 6 Reagents/Calibration

Reagents

Overview

This section includes:

- Reagent Status/Calibration Status Screen
- Loading Reagent/Calibrator Bar Coded Parameters
- Displaying/Deleting Reagent Parameters
- Loading/Clearing Buffers and Diluents
- Loading Wash Solution
- Loading/Unloading Reagent Cartridges

Reagent Status/Calibration Status Screen

To display the screen select **Rgts/Cal** from the menu bar. (Refer to Figure 6.1.)

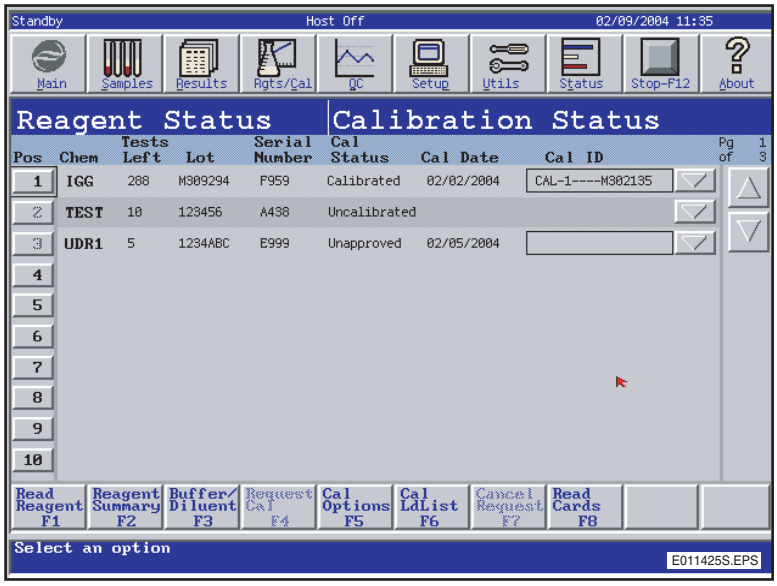


Figure 6.1 Reagent Status/Calibration Status Screen

Loading Reagent/Calibrator Bar Coded Parameters

- A reagent bar code card is provided with every reagent kit. The reagent bar code card contains lot specific parameters for each reagent.
- A calibrator bar code card is provided with every calibrator. The calibrator bar code card contains lot specific parameters for each calibrator.

Limits

- Up to 8 reagent or calibrator bar code cards can be loaded on the sample carousel at one time.
- Up to 6 different lots of the same reagent or calibrator ID can be stored at one time. When more than 6 different lots are scanned, the oldest, by date of scan, is removed from the database.
- Up to 50 different calibrator names can be stored in the database.

Loading Bar Code Cards

The instrument status must be *Standby* in order to proceed with the steps below to load reagent and calibrator bar code cards.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Place the reagent or calibrator bar code card(s) on an EMPTY rack(s). (Refer to Figure 6.2.)</td></tr>
<tr><td>2</td><td>Open the sample compartment cover. Rotate the sample carousel by pressing the advance button on the instrument.</td></tr>
<tr><td>3</td><td>Place the rack(s) on the sample carousel.</td></tr>
<tr><td>4</td><td>Close the sample compartment cover.</td></tr>
<tr><td>5</td><td>Select Rgts/Cal from the menu bar.</td></tr>
<tr><td>6</td><td>Select Read Cards [F8].</td></tr>
<tr><td>7</td><td>Select <OK> to start the bar code read and go to Step 8.
OR
Select <Cancel> to return to the Reagent Status/Calibration Status screen without reading the bar code cards.</td></tr>
<tr><td>8</td><td><table><tr><th>If the bar code card is...</th><th>the screen will display...</th></tr><tr><td>successfully read</td><td>the Rack, reagent/calibrator Name, and Lot for each scanned bar code card in the Cards Read window.</td></tr><tr><td>misread</td><td>an error message appears with the rack and position where the bar code was misread. (Refer to CHAPTER 10, Utilities, Troubleshooting.)</td></tr></table></td></tr>
<tr><td>9</td><td>To exit the Cards Read dialog box, even if the bar code read is not finished, select <OK>.</td></tr>
</table>

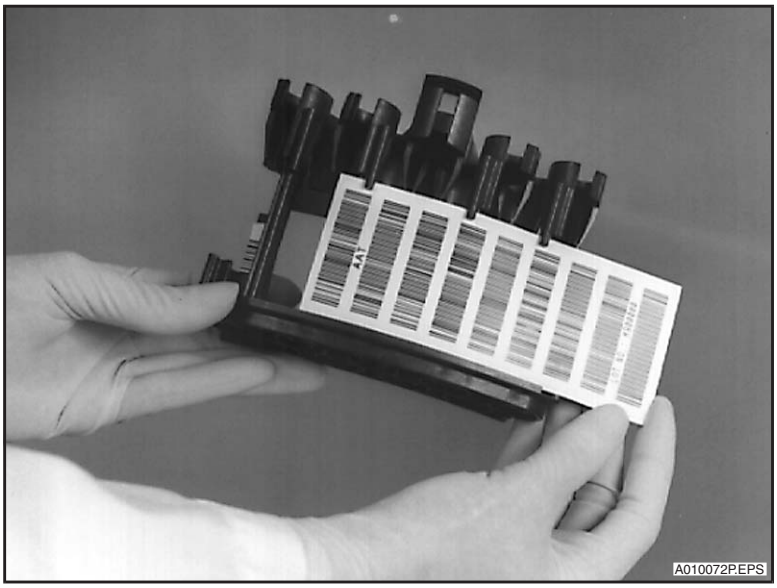


Figure 6.2 Loading Reagent/Calibrator Bar Code Cards on a Rack

Displaying/Deleting Reagent Parameters

Reagent parameters may be displayed and/or deleted from the Reagent Summary. (Refer to Figure 6.3.)

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

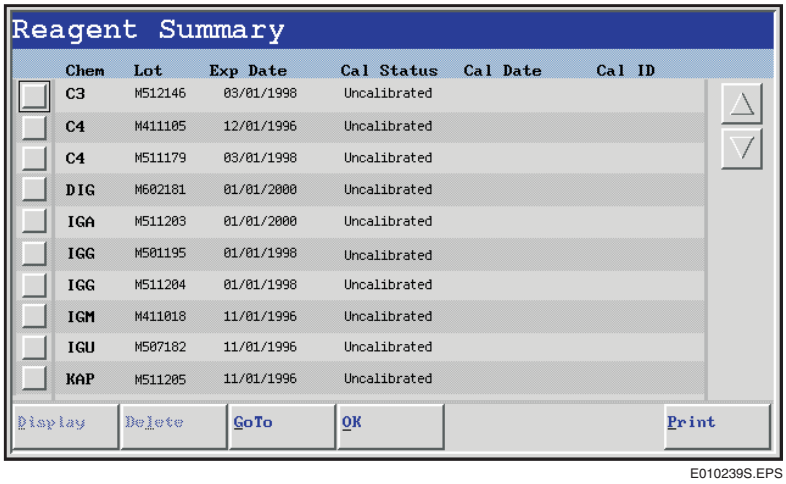


Figure 6.3 Reagent Summary Dialog Box

Loading/Clearing Buffers and Diluents

Reaction buffers and sample diluents must be placed on the IMMAGE 800 and their positions and lot numbers must be entered into the computer.

- Up to 4 bottles of reaction buffer may be placed on the inner section of the reagent carousel.
- Up to 4 bottles of sample diluent may be placed on the inner section of the sample carousel.
- For certain chemistries, a buffer is used as sample diluent and is placed on the inner section of the sample carousel. (Refer to the IMMAGE Immunochemistry Systems *Chemistry Information Manual* for further details.)

Limits

- Only one lot number of each buffer type and one lot number of each diluent type may be loaded onto the system at one time.
- Multiple bottles of the same lot can be loaded at different positions.
- When multiple positions are defined for the same buffer or diluent, the lot number will be automatically copied to each position.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Loading Wash Solution

Load a new box of wash solution when the volume of the solution is low (approximately 1000 tests/10 liter box).

The instrument status must be *Standby* in order to proceed with the steps below to load the wash solution.

Step	Action
1	Remove the screw cap, with the tubings and straw attached, from the wash solution container in use.
2	Remove the screw cap from the new container of wash solution.
3	Place the cap with the tubings and straw attached into the new wash solution and screw on the cap. The blue tubing is attached to the side with a straw, the orange tubing is not attached to a straw.
4	Verify that the blue and orange tubings are attached to the top of the cap.
5	No software intervention is required. Priming is not required.

Loading Reagent Cartridges

- Only one lot of any reagent may be placed on the reagent carousel.
- Multiple cartridges of the same lot may be placed on the carousel.

To load bar coded reagent cartridges on the reagent carousel, follow the steps below.

Step	Action
1	Invert each cartridge gently before removing screw caps.
2	Remove the screw caps from the cartridge(s).
3	Check each cartridge compartment for bubbles and remove bubbles if present.
4	Place evaporation caps on each reagent cartridge compartment.
5	Place reagent cartridges onto the reagent carousel. Ensure that the reagent cartridge is correctly placed into the groove on the carousel.
6	Select **Rgts/Cal** from the menu bar.
7	Select **Read Reagent [F1]**.
8	Select **<OK>** to initiate the reagent cartridge read.

Removing the Reagent Carousel

Upon completion of the daily workload remove either the Reagent Carousel or the individual Reagent Cartridges and store in the refrigerator.

Calibration

Overview

This section includes the following topics:

- Checking Calibration Status
- Requesting and Canceling Calibration
- Loading Calibrators on the Sample Carousel
- Starting a Calibration Run
- Calibration Results
- Re-enabling Calibration
- Cal Options

Checking Calibration Status

The calibration status of each on-board reagent cartridge can be checked prior to performing a run. Refer to Figure 6.1 and the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Requesting and Canceling Calibration

- Reagent and calibrator bar code parameters must be loaded prior to requesting a calibration.
- Calibration must be requested for a reagent lot which has a status of Uncalibrated before patient samples can be run with that reagent lot.
- Calibration may be requested regardless of the current calibration status for any reagent lot.
- If the calibration status is Cal Failed, request either a new calibration or Cal Re-enable.

Requesting Calibration

From the **Rgt/Cal** screen select **Request Cal [F4]**. Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Checking and Clearing Racks

The rack position used for a calibrator must be Available before it is used for calibration. Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

- On the Request Calibration screen, check the **Available Racks** section to see if the rack to be used is *Available*.
- If the rack is *Not Available*, select **Clear Racks [F1]**.

Assigning Calibrator Rack and Position

A non-bar coded calibrator must be assigned a rack and position when requesting calibration. Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Loading Calibrators on the Sample Carousel

When calibration is requested, calibrators are placed on the sample carousel.

Placing Bar Coded Calibrators on the Carousel

Calibration status must be *Requested* in order to proceed with the steps below to place bar coded calibrators on the sample carousel prior to automatic assignment.

Step	Action
1	Locate the calibrator bar code label provided with the calibrator.
2	Place the appropriate label on an empty test tube. Note: The labeled test tube should be saved for re-use.
3	Place the tube into a sample rack.
4	Place the appropriate sample cup in the labeled test tube.
5	Place the appropriate calibrator in the sample cup.
6	Repeat Steps 1-5 for any additional calibrators. Continue placing calibrators into the same sample rack.
7	Open the sample compartment cover.
8	Place the rack(s) containing calibrators on the sample carousel. Rotate the sample carousel by pressing the advance button on the instrument. Controls and/or patient samples may be placed in other positions on the sample carousel.
9	Close the sample compartment cover.

For Non-bar Coded Calibrators refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Starting a Calibration Run

After the calibration has been requested and calibrators are placed into position, select **Main** from the menu bar, and then select **Run**.

Calibration Results

The calibration information is printed on the Calibration Report after a successful calibration.

When calibration fails, samples programmed for a reagent that fails calibration will be displayed and printed on the report as *Pending*.

Calibration History

Introduction

The Calibration History window allows the operator to review the previous four calibrations and displays the following information:

- chemistry name
- reagent lot number
- date
- time
- Cal ID
- scale factor
- reaction buffer
- sample diluent

Displaying Calibration History

Calibration history is not available for User-Defined Reagents. Up to four successful calibrations will be displayed. Failed calibrations will not be displayed.

Step	Action
1	Select **Rgts/Cal** icon.
2	From the Reagent Status/Calibration Status screen, select the pull-down on the **Cal ID** field to display the Calibration History window.
3	The calibrations display ascending date/time order, with the oldest calibration listed first.
4	Select **<OK>** to return to the Reagent/Status/Calibration screen.

Re-enabling Calibration

The previous successful calibration can be re-enabled only when a calibration fails.

From the **Rgt/Cal** screen, select the options button **<▼>** to the right of the Cal ID of the failed calibration, then select **<OK>** to re-enable the calibration.

After calibration is re-enabled, the previous calibration is re-enabled for all reagent cartridges of the same lot.

Cal Options

Cal Options is used to access Calibrator Summary (calibrator lot parameters), Slope and Offset Adjustments, or Print Last Calibration Results.

From the Rgts/Cal screen select **Cal Options [F5]**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

CHAPTER 7 Preparing for Programming/Running

Overview

Introduction

Before programming samples and/or starting a run:

- all racks to be used must have a status of *Available*. If the status of a rack is not *Available*, the rack must be cleared before it can be used for programming samples.
- the dilution segments status should be checked. Segments can be cleared or left unchanged.
- reagents, reaction buffers, and sample diluents should be checked.
- wash solution volume should be checked.

Checking and Clearing Sample Racks

> NOTICE
> If only bar coded samples are used (racks and positions are automatically assigned), it is not necessary to clear racks.

To clear sample racks:

From the Program Sample screen (refer to Figure 7.1), select **Clear Samples [F7]**.

Choose the **Rack(s) field**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Replacing Dilution Segments

There are two options from the Dilution Segments status screen:

- The status of the dilution segments can be left unchanged.
- Up to four dilution segments can be cleared. The cleared segments must be replaced with unused segments on the sample carousel.

From the Program Sample screen select **Status** from the top menu bar (refer to Figure 7.1), and select **<1> Dilution Segments**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Checking Reagents, Buffers, and Diluents

Before starting a run, the Reagent Status / Calibration Status and Buffer / Diluent Status should be checked to ensure that:

- the appropriate chemistries, buffers, and diluents are on the system.
- the volume of reagents, buffers, and diluents seem adequate to complete the run.
- the chemistries are calibrated.

Checking Reagent Status

To check the status of reagents:

Select **Rgts/Cal** from the top menu bar (refer to Figure 7.1), and select **Read Reagents [F1]** to update the status information if reagent cartridges were loaded or removed since the last run.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Checking Buffer/Diluent Status

To check the status of buffers and diluents:

Select **Rgts/Cal** from the top menu bar (refer to Figure 7.1), and select **Buffer/Diluent [F3]**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Checking Wash Solution Volume

Before starting a run, the wash solution should be checked to ensure that there is sufficient volume to complete the run.

Replace the box if the wash solution volume does not appear sufficient to complete the run.

Wash solution can be pooled.

Programming a Sample

Overview

This section includes:

- sample identification
- test selection
- sample description, which consists of sample type, sample comment, patient ID, and patient demographics
- sample options, which consist of sample replicates, test replicates, off-line dilution ratio, antigen excess testing, non-standard dilutions, and linking samples
- control samples
- STAT samples

Program Sample Screen

To access the Program Sample screen, select **Samples** from the menu bar. (Refer to Figure 7.1.)

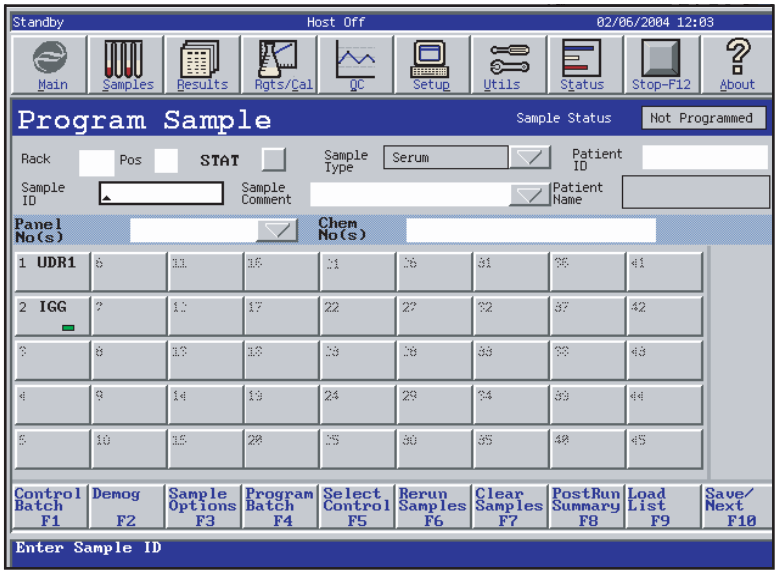


Figure 7.1 Program Sample Screen

Entering Sample Identification

Every sample must be identified by either Rack and Position or Sample ID. Both Rack and Position and a Sample ID can be entered for a sample.

Minimum Sample Program Required

The minimum information required for a sample to be saved is Rack and Position and at least one chemistry OR Sample ID and at least one chemistry.

Assigning a Rack and Position

> NOTICE
> A Rack number and Position number must be assigned if a sample is not bar coded or if a sample bar code is unreadable.

To assign a Rack number and Position number, select **Samples** from the top menu bar (refer to Figure 7.1), and select the **Rack field** if the cursor is in another field.

- Type an available Rack number (1-99) and press **[Enter]**.
- Type a positon number (1-9).

Entering a Sample ID

Select **Samples** from the top menu bar (refer to Figure 7.1), and select the **Sample ID field** if the cursor is in another field.

> NOTICE
> Every Sample ID must be unique. A Sample ID can only be reused by:
> - rerunning the sample. The original and rerun results will be collated, or
> - clearing the Sample ID and reprogramming it. The original and reprogrammed Sample IDs will be treated as two different samples.

A previously saved sample program can be displayed by entering either the Rack and Position or the Sample ID. The program can then be edited.

Selecting Chemistry Tests by Panel

A panel containing one or multiple chemistry tests can be selected. Panels are defined by the user in Setup.

A panel can be selected by typing the number of the panel in the **Panel No(s) field** or by selecting the panel from the Panels list.

> NOTICE
> If multiple panels are selected, their defined sample types, non-standard dilutions, antigen excess and any off-line dilutions must be the same.

A selected panel can be canceled by deselecting it in the Panels list. The highlight will be removed.

Selecting Chemistry Tests by Chemistry

A chemistry test can be selected individually from the chemistry menu. Chemistries are configured on the chemistry menu by the user in Setup.

A chemistry can be selected by typing the number of the chemistry in the **Chem No(s) field** or by selecting the appropriate button in the chemistry menu.

> NOTICE
> If both panels and individual chemistries are selected for a sample, their Sample Types and any off-line dilutions must be the same.

Selecting a Sample Type

The default Sample Type is defined in Setup and is initially displayed in the **Sample Type field**.

> NOTICE
> If a sample type is selected that is not applicable to specific chemistries, those chemistries are unavailable and appear dimmed on the chemistry menu.

Timed Urine Parameters

If Timed Urine is selected as the Sample Type, a dialog box will appear. If the parameters are not entered, the sample program cannot be saved.

Entering a Sample Comment

A Sample Comment can be selected from a list defined in Setup or can be entered in the **Sample Comment field**.

Entering a Patient ID

A Patient ID can be entered in the **Patient ID field** and can be used as a link to recall demographics.

Entering Patient Demographics

Patient Demographics can be entered for each sample.

Select **Demog [F2]** to access the Demographics screen.

Individual patient demographic fields can be disabled from Setup. Disabled demographic fields cannot be accessed.

Selecting Sample Options

Selecting Sample Options

To access the Sample Options dialog box, chemistries must first be selected from the Program Sample screen.

Selecting Replicates

A Sample Replicate number can be entered in the **Sample Replicate field**. The Sample Replicate number defines the number of times all tests selected for the sample will be repeated. (1-9 Sample Replicates are available.) It applies only to the current sample.

The default number of sample replicates defined in Setup is displayed in the **System Replicates field**. This field is for display only and cannot be accessed, except from Setup.

A test replicate number can be entered for each test that is selected for a sample. The test replicate number defines the number of times an individual test will be repeated. (1-9 test replicates are available). It applies only to the current sample.

> NOTICE
> The test replicates function is available only when the Sample Replicate is set to 1.

Antigen Excess (AGXS) Testing

Antigen excess (AGXS) testing can be enabled or disabled for an individual chemistry. The enabling or disabling of AGXS from Sample Options applies only to the current sample.

If AGXS testing is applicable to a chemistry, a check box appears beside that chemistry in the Sample Options dialog box.

Selecting Non-Standard Dilutions

A Non-Standard Dilution can be selected for an individual chemistry from a pre-defined list. The list contains Non-Standard Dilutions that are specific for each chemistry. The default starting dilution is indicated as selected when the Non-Standard Dilutions screen is first displayed.

When a Non-Standard Dilution is selected for a chemistry:

- it is used as the starting dilution for the chemistry.
- it applies only to the chemistry for the current sample.
- it is displayed beside the chemistry on the Sample Options dialog box.
- it will remain selected if the Non-Standard Dilution dialog box is displayed again for the same sample.

If antigen excess testing is enabled for a chemistry, it will still be performed when a Non-Standard Dilution is selected.

Sample programming from a host computer assumes the default starting dilution for each chemistry. A Non-Standard Dilution can be selected by editing the sample program before the run begins.

A Non-Standard Dilution can be useful when a specific sample is known to have unusually low or high test results.

Entering an Off-line Dilution Factor

Introduction

An Off-line Dilution Factor may be entered for a sample through the Sample Options screen. This factor represents a user prepared dilution of the sample. The Default Dilution normally used in the calculation of concentration for an analyte should be considered in the creation of a user prepared dilution.

The Off-Line Dilution Factor applies to the current sample only. When a sample using an off-line dilution factor is run, the system makes **no** further dilutions. It runs the sample "as is"; it does **not** create the default dilution or any out-of-range dilutions. Each result is automatically multiplied by the user-entered off-line dilution factor.

Example:
To assay an IGA sample at twice the default dilution:

- To make twice the dilution of the analyte being assayed the user must know the Default Dilution and appropriate diluting fluid for the analyte.
- Find the Default Dilution and diluting fluid for IGA in IMMAGE Immunochemistry Systems *Chemistry Information Manual*, APPENDIX B, *Measuring Ranges/Dilution Fluids*.
  - The Default Dilution for IGA is 1:36.
  - The diluting fluid for IGA is DIL1.
- Prepare the Default Dilution for the analyte being tested.
  - For IGA, make a 1:36 dilution by diluting 1 part serum in 35 parts of DIL1.
- Prepare a 1:2 dilution of the previously prepared Default Dilution.
  - Dilute 1 part of Default Dilution in 1 part of DIL1.
  - The final dilution factor is now 1:72.
- Enter an Off-line Dilution Factor of 72 during sample programming.
- The system will produce a final result by automatically multiplying each test result from the sample by 72.

Alternatively the user may run an off-line dilution without selecting to use this feature. The system will perform tests using the default dilution and out-of-range dilutions as required. The user would then need to manually multiply all test results for the sample by the user-prepared dilution factor.

Entering Off-line Dilution Factor

Follow the steps below to enter an Off-line Dilution Factor.

Step	Action
1	Select **Sample Options [F3]** from the Program Sample screen.
2	Choose the **Off-line Dilution Factor** field.
3	Enter the factor by typing the number of total parts of diluent + sample (1.01-9999.99), and press **[Enter]**.

CAUTION

If a non-standard or off-line dilution is selected, a condition of antigen excess could exist which may not be detected by the IMMAGE 800 System.

When an off-line dilution is selected, diluent incompatibility is not detected by the IMMAGE 800 System. Only chemistries using the same diluent type should be run on a sample with an off-line dilution preparation. Refer to the IMMAGE Immunochemistry Systems, *Chemistry Information Manual*, Appendix F, *System Reagent Configuration and Part Numbers* for a list of chemistries using the same diluent type.

Linking/Unlinking Samples

Some special calculations use the test results from two different samples. The Sample IDs of both samples must be linked so the calculation can be performed.

Samples can also be unlinked.

Step	Action
1	Program one of the samples to be linked. Select **Save/Next [F10]**.
2	Enter a Sample ID, select chemistries, and program any additional information for the other sample to be linked.
3	Select **Sample Options [F3]**.
4	Select **<Link Samples>**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Setting Variables

Variables are used in Custom Calculations as placeholders in formulas to represent more than one number (value). The numeric value of the variables can be entered on the Set Variables screen.

A maximum of six variable values may be entered. The values apply only to the current sample.

Step	Action
1	Select the desired chemistry(ies) from the Program Sample screen.
2	Select **Sample Options [F3]**.
3	Select **<Set Variables>**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Programming a Control

Controls must be defined before being programmed to run. Refer to CHAPTER 9, *Quality Control*, for further instruction.

- Controls may be identified by bar code labels or by Rack and Position.
- Control results are compared to the ranges defined by the mean and standard deviation.
- Control IDs, like Sample IDs, must be unique for each sample within a run.
- Control IDs, unlike Sample IDs, can be reused after the control sample is run. When the sample status of a Control ID is *Complete* or *Incomplete*:
  - the Control ID can be selected to run again.
  - the status will automatically change to *Sample Required*.
  - any *Pending* tests are deleted from an *Incomplete* control sample program.

Exception: if controls are programmed by bar code, the system will try to run *Pending* tests from an Incomplete sample.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Bar Coded Controls

Bar code labels can be used to identify control samples. The bar code must encode a defined Control ID.

If the same control is repeated in different positions during a run, each control sample must have a different bar coded Control ID.

All defined control chemistries will be run automatically when a Control ID is identified by bar code.

NOTICE

After pausing or stopping the system, completed bar coded control samples will be run again when the system is started.

Non-bar Coded Controls

Step	Action
1	Select **Select Control [F5]** from the Program Sample screen..
2	Type the number of the desired control and press **[Enter]**.
3	Enter a Rack and Position number. AND Select the options button **<▼>** beside the Control ID field to select a Control ID. (A Control ID is optional.) NOTICE If a control is programmed with a Control ID and the host sends a patient sample with an ID identical to the control, the programmed control will be deleted.
4	Select **Save [F10]** to save the control program and return to the Program Sample screen.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Programing a STAT

A sample which requires priority can be programmed as a STAT. The running priority for samples is:

- A STAT sample is run before any routine patient or control sample on the carousel, regardless of the Rack and Position numbers.
- A STAT calibration is run before a STAT sample. A STAT calibration must be programmed when the calibration is requested.
- If multiple STAT samples are programmed, they will be run in the order they are placed around the sample carousel, in a counter-clockwise direction.

Select **Samples** from the menu bar. Select the **STAT** check box.

Selecting Save/Next

When all desired information is programmed for a sample, select **Save/Next [F10]** to program additional samples.

A message will display if there is not enough information entered to save the sample program.

If a minimum of a sample identifier (Rack and Position or Sample ID) and a chemistry is programmed for a sample, the sample program will be automatically saved if the Program Sample screen is exited without selecting **Save/Next [F10]**.

Programming a Batch of Samples

Programming a Batch of Samples

Multiple samples can be programmed as a batch with the same chemistries, Sample Type, Sample Comment, and Sample Options.

Up to 100 samples can be programmed in a batch. A maximum of 72 samples can be placed on the sample carousel at one time. Additional samples in a batch can be placed on a subsequent run.

Batches and individual samples can be programmed in the same run.

Select **Samples** from the menu bar. Select chemistries from the Program Sample screen and then **Program Batch [F4]**.

Identifying Batch Samples

The procedure for identifying samples in a batch is different when Bar Code Priority is enabled in Setup than when Bar Code Priority is disabled.

If Bar Code Priority is enabled: Type the Sample ID for each sample in the batch.

If Bar Code Priority is disabled: Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further information.

Rerunning a Sample

A sample can be rerun when it has a status of *Complete* or *Incomplete*. If the system is running, a sample programmed to be rerun will be added to the current run. If the system has returned to a *Standby* status, a new run must be started.

Several options are available when rerunning samples:

- The original sample programs can be edited before rerunning.
- The original sample programs can be rerun.
- Selected chemistries can be rerun for a group of samples.
- The initial dilution made in the dilution well can be reused. The default is to remake a dilution.

> **⚠ CAUTION**
>
> **Due to the possibility of sample evaporation over time, the Reuse Dilution feature should be used with discretion.**

Rerun Results
When tests are rerun:

- The rerun results replace the original results.
- Rerun results are indicated by a flag (R) on the Laboratory Report.
- After a sample is rerun, all results will be collated on the result report.

To rerun samples, select **Rerun Samples [F6]** from the Program screen.

> NOTICE
> When rerunning samples by Rack and Position, the samples must be kept in their original rack number and position number on the sample carousel.

Rerunning with Non-Standard Dilutions
If the original sample was programmed to run with a standard dilution, and later you changed the defaulted standard to a non-standard dilution, the sample will rerun with the standard dilution.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Requesting a Load List

A Load List Summary can be requested at any time and contains programmed information for each sample.

Select **Load List [F9]** from the Program Sample screen.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Requesting a Post-run Summary

The Post Run Summary feature provides a list of samples that are pending or incomplete in reverse chronological order. Refer to "Default Setup" in CHAPTER 5.

From the Program Sample screen, select **Post Run Summary [F8]**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Clearing a Sample

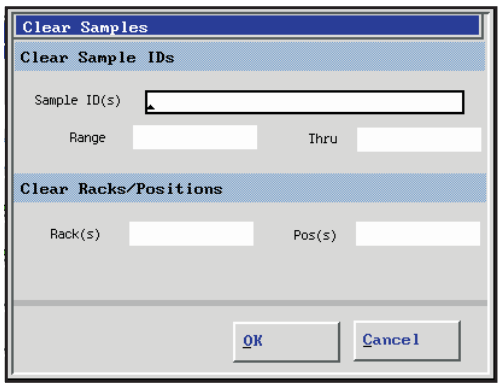
A sample can be cleared by Sample ID and/or a range of Sample IDs, or by Rack and Position. (Refer to Figure 7.2.) Up to 10,000 Sample IDs can be stored in the database.

When a sample is cleared by Sample ID:

- the associated Position on the Rack becomes available for programming.
- the Sample ID can be reused.
- the Sample Program cannot be recalled by Rack and Position or Sample ID.

When a sample is cleared by Rack and Position:

- the associated Position on the Rack becomes available for programming.
- the Sample ID cannot be reused.
- the sample program cannot be recalled by Rack and Position.



E010266S.EPS

Figure 7.2 Clear Samples Dialog Box

Loading Samples

Load Samples

To load prepared sample containers into racks and onto the IMMAGE 800, follow these steps.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Determine in which rack and position to place sample containers.

<table>
<tr><th>If the sample container...</th><th>Then...</th></tr>
<tr><td>is bar code labeled,</td><td>Samples may be placed in any position of any rack of the proper size (no Load List is required).</td></tr>
<tr><td>is not bar code labeled,</td><td>• Select Samples from the menu bar,
• Select Load List [F9] from the Program Samples screen,
• Type the number(s) of the rack(s) programmed for the samples to be processed, and
• Print or display the Load List to identify the proper position for each sample.</td></tr>
</table>
</td></tr>
<tr><td>2</td><td>Place prepared sample containers into sample racks and verify that each container is:

• placed into a rack which matches the container size (four rack sizes are available: 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, and 16 × 100 mm),
• seated in the depression at the bottom of the rack, and
• positioned so that bar code labels (1), if used, face in the same direction as the rack bar code label (2). Position numbers (3).

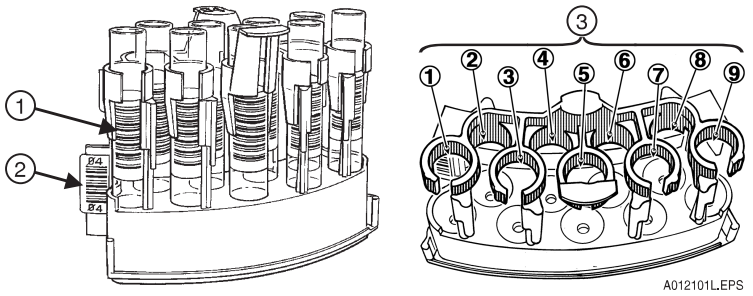
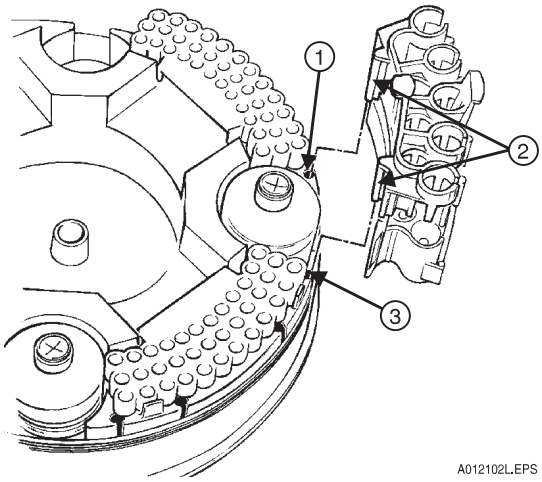
 

Figure 7.3</td></tr>
</table>

(1 of 2)

Step	**Action**, continued
3	• Confirm the instrument status is in *Standby*. • Place the sample rack in any position on the sample carousel. Notes: Position the rack so that both rack pegs (2) slide into holes in the carousel (1), (3). Press the advance button to rotate the carousel to additional positions. Racks containing calibrators must be placed in sample carousel positions A and/or B only.  Figure 7.4

(2 of 2)

Pre-run Checklist

Pre-run Checklist

With the IMMAGE 800 in *Standby*, prepare for the start of a run by performing these tasks or verifying they have been performed. Refer to appropriate sections of this guide for instructions on how to perform each task.

- Perform daily maintenance.
- Check status of dilution segments, clear and replace if necessary.
- Check status of reagent cartridges, load if necessary.
- Check status of reaction buffers and sample diluents, replace if necessary.
- Check sample rack status, clear racks if necessary.
- Check calibration status, calibrate if necessary.
- Prepare sample containers.
- Program control or patient requests, if necessary.
- Load samples.

Starting the Run

When all sample racks are on the sample carousel and the run is ready to be processed, follow the steps below.

Step	Action
1	Close the covers.
2	Select **Main** from the menu bar.
3	Select **<Run>**.
4	Select **<OK>** if dilution segment status is *OK*, AND Observe the instrument occasionally during the first 5 minutes of operation to respond to any messages that might be displayed.

Pausing a Run

Overview

Introduction

When the system is running the user may select the pause option to load samples without waiting for the entire system to complete all actions.

When pausing a run:

- The user can pause the system for a sample load.
- The user can pause the system completely.
- The user can cancel the pause request.

System Pause

Introduction

If the system is running and the user selects the pause option from the IMMAGE 800 main screen, the user may choose to completely pause the system. When the user selects pause, the system completes any sample that is in process and goes into *Standby* after the pause.

Step	Action
1	During the run, select **Pause** at the main screen.
2	Select **System Pause** at the Request Pause screen. (Refer to Figure 7.5.) The system status changes to *Pausing*. The system completes any sample that is in process, then goes into Standby mode.

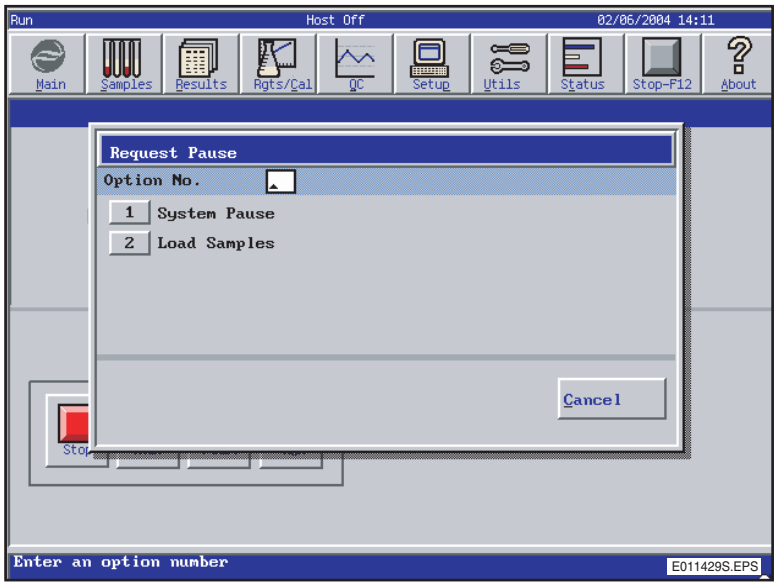


Figure 7.5 Request Pause Screen

Canceling a Pause Request

Select the **<Cancel>** button to cancel the pause request. This will not affect the current run. (Refer to Figure 7.5.)

Restarting a Run

Select the **<RUN>** button to restart the paused run.

Pausing to Load Samples

Introduction

If the system is running and the user selects the pause option from the IMMAGE 800 main screen, the user may choose to pause the system for a sample load. This type of pause allows the user to load samples without waiting for the entire sytem to complete all actions. The system provides an estimated time period before samples can be loaded, based on the time when sample additions/removal is allowed.

Tests currently running on the reaction wheel will continue. No further dilutions are created. While the remaining tests continue, samples may be added or removed. The user has the option to resume operations or let the system pause to *Standby*.

Pausing-Load Samples

Step	Action
1	Program new samples on a rack that is not on the system.
2	During the run, select **<Pause>** from Main screen. It is recommended not to pause the system during calibration because it may result in a calibration failure.
3	Select **Load Samples** at the Request Pause screen. (Refer to Figure 7.5.) Note that the status screen shows "Pausing-Load Samples" and the estimated time period before you can add or remove samples. The time counts down in 5 second increments to zero. OR Select the **<Cancel>** button to cancel the pause request. This will not affect the current run. (Refer to Figure 7.5.)
4	Wait until the "OK to load samples" message appears on the screen. (Refer to Figure 7.6.) **⚠ CAUTION** **To avoid personal injury, DO NOT load or remove samples until the "OK to load samples" message appears on the screen.** When the message appears, select **<OK>**. The system status changes to "Pausing-OK to load samples."
5	Advance the sample wheel and load samples. NOTICE The amount of time to load new samples and to resume the run depends on the number of samples being processed. If a small number of samples are being processed, there may not be enough time to resume the run. In this case, the sytem will return to *Standby*. Select **<RUN>** to restart the system.

(1 of 2)

Step	Action, continued
6	Go the the Main screen and select **<RUN>**. The system status will change to *Resuming* and *Run*. **CAUTION** **To avoid personal injury, DO NOT load samples once the RUN button is selected.**

(2 of 2)

Figure 7.6 OK to Load Samples Message

Canceling a Pause

Select the **<Cancel>** button to cancel the pause request. This will not affect the current run. (Refer to Figure 7.5.)

Resume Operations

If the user chooses to resume operations before the system goes to *Standby*, the system continues the pause process until all currently running tests are complete. When all operations are complete, the system reinventories the sample wheel and automatically returns to the running state. If the user resumes operations after the system goes to *Standby*, the system reinventories the sample wheel and returns to a running state. Incomplete samples requiring additional dilutions continue processing at the next required sample dilution.

Dilutions created before selecting *Pause*, will not be reused. In some instances, the system may have to remake previously made dilutions, and additional sample volume may be required.

CHAPTER 8 Results Recall

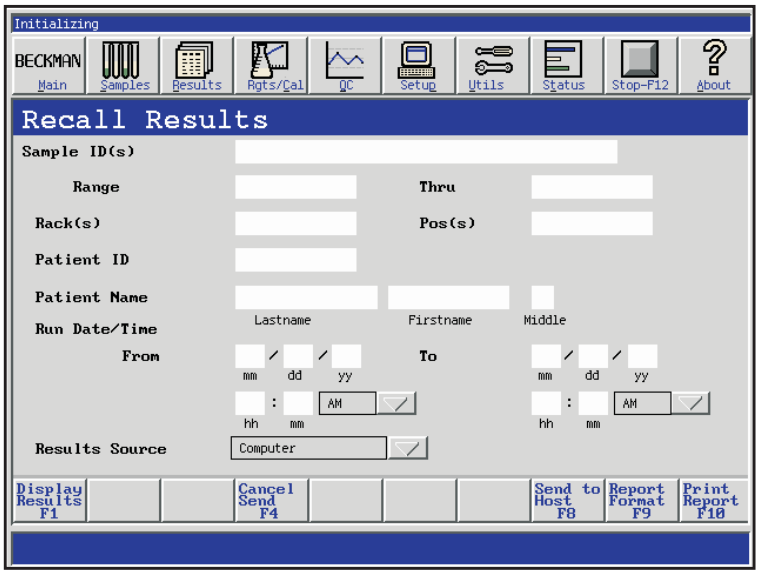
Overview

Introduction

Results can be recalled by sample ID, rack and position, patient ID, patient name, or run date and time. Results which have been recalled can be sent to a host computer. Up to 10,000 patient samples may be stored by the IMMAGE 800 database.

To recall results, select **Results** from the menu bar; Recall Results screen (Figure 8.1) will appear.

Select a function button from the bottom of the screen.



E014099S.EPS

Figure 8.1 Recall Results

To recall results in the current database stored in the hard disk, select **Computer**.

To recall results from diskettes that have been restored into the hard disk, select **Diskette**.

NOTICE
Patient results restored from diskettes cannot be sent to the host.

Displaying Recalled Results on the Screen

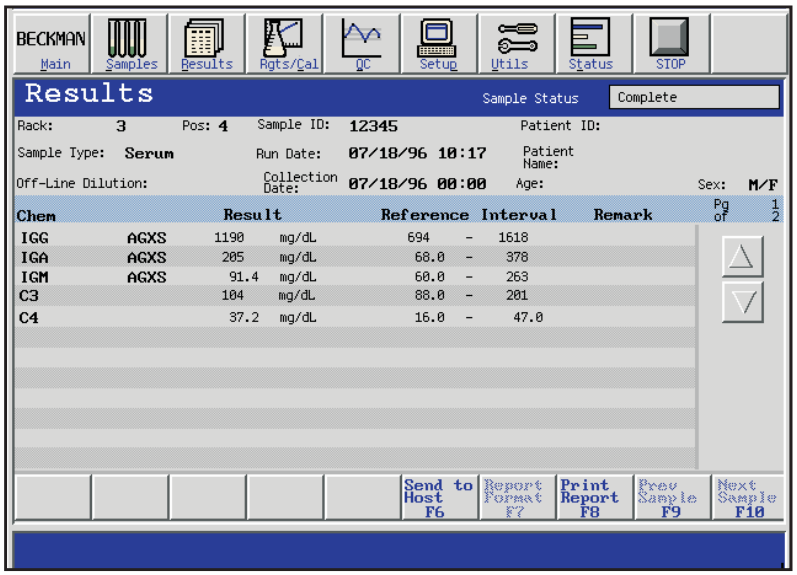
Introduction

All recalled results may be viewed on the screen.

Displaying Results

From the Recall Results screen, select the results to be viewed. Select **Display Results [F1]**.

Select a function button from the bottom of the screen.



E010286S.EPS

Figure 8.2 Results Screen

Printing Recalled Results

Introduction

All results may be printed.

Printing a Recalled Result

To print all selected results:

- Select all results to be printed from the Recall Results screen (refer to Figure 8.1).
- Select **Print Reports [F10]**.

To print an individual report:

- Select the result to be printed from the Recall Results screen (refer to Figure 8.1).
- Select **Display Results [F1]**.
- Select **Print Report [F8]** (refer to Figure 8.2).

Stopping a Print Request

Printing of recalled results can be stopped from the Recall Results screen by selecting **Utilities** from the menu bar and **<10> Stop Print**.

Refer to IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Sending Results to the Host

Introduction

Results from the IMMAGE 800 are automatically sent to the host computer when the autosend is enabled in Host Communications setup.

Results can be sent manually to the host computer whether autosend is enabled or disabled.

For further information refer to CHAPTER 5, *System Software Configuration*, "Host Communications Setup".

CHAPTER 9 Quality Control

Overview

Introduction

The Quality Control (QC) program summarizes quality control results generated on the IMMAGE® 800 Immunochemistry System. The control program uses the Westgard Rules[1] to monitor statistics for up to 100 controls. Rule violations 1-2S and 1-3S are flagged on a real-time basis and can be displayed on the console monitor.

The QC program provides the following features:

- Review Control
- Define/Edit
- Delete Control
- QC File List
- QC Log
- QC Summary
- QC Chart (Levey-Jennings)
- Backup QC
- Print Control

Recommended QC and Analysis Intervals

Beckman Coulter, Inc. recommends that at least two levels of control material be analyzed daily. In addition, these controls should be run with each new calibration, with each new lot of reagent, and run after specific maintenance or troubleshooting, as detailed in the IMMAGE 800 Immunochemistry System *Operations Manual*. More frequent use of controls, or the use of additional controls, is left to the discretion of the user based on individual laboratory practice.

QC Data Source

The system allows the operator to review and print QC data stored on:

- Hard Disk
- External Media (Floppy Diskettes)

QC Statistics and Rules

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for QC rules used by the Quality Control feature.

[1] Westgard, J. O.; Barry, P. L.; Hunt, M.R.; Groth, T. A., *A Multirule Shewhart Chart for Quality Control in Clinical Chemistry*. Clinical Chemistry 1981; 27:493-501.

Also, http://www.westgard.com/pdf

Defining a Control

Overview

The Define/Edit option allows definition of up to 100 control names. (Refer to Figure 9.1.) The minimum information required to save a control definition is:

- control name
- lot number
- sample type
- one chemistry selection
- QC file number
- Mean
- Standard Deviation (SD)

In addition, the assigned mean, standard deviation (SD), and constituent code can be defined for each chemistry in a control. Control IDs can also be assigned to a control. (Refer to Figure 9.2.)

Grouping Chemistries Under a Control Name

All chemistries appearing in a control definition must be of the same sample type and have the same sample preparation. (Refer to the IMMAGE Immunochemistry Systems *Chemistry Information Manual* for further details.)

QC File Number

The QC file number is a number from 1-999 which is unique to a chemistry defined within a control name. If the QC file number has already been assigned, the database will not accept it a second time. The file number can be reused after a chemistry in a control is deleted.

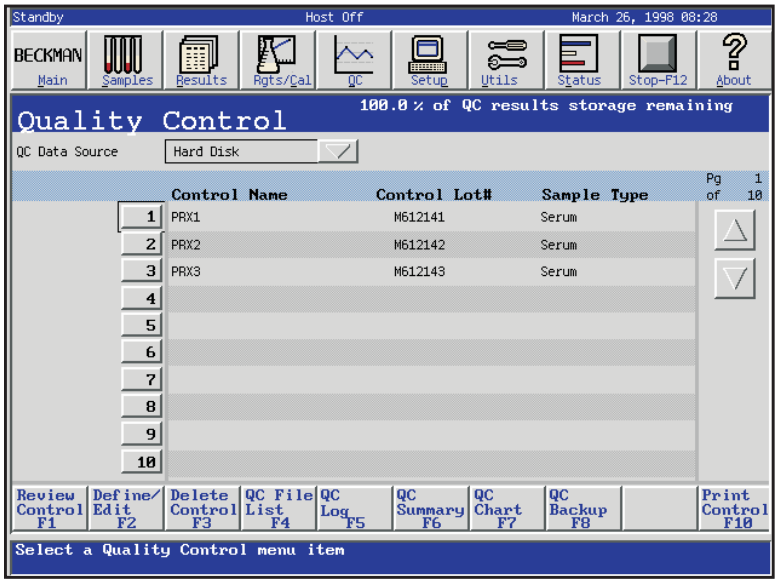
Assigned Mean and Assigned SD

For initial setup of control definitions, the mean and standard deviation (SD) values from commercial quality control inserts may be used. When the laboratory establishes its own mean and SD ranges, these values should be used instead of the insert values.

The mean and SD values may be edited, as data is collected for the individual laboratory.

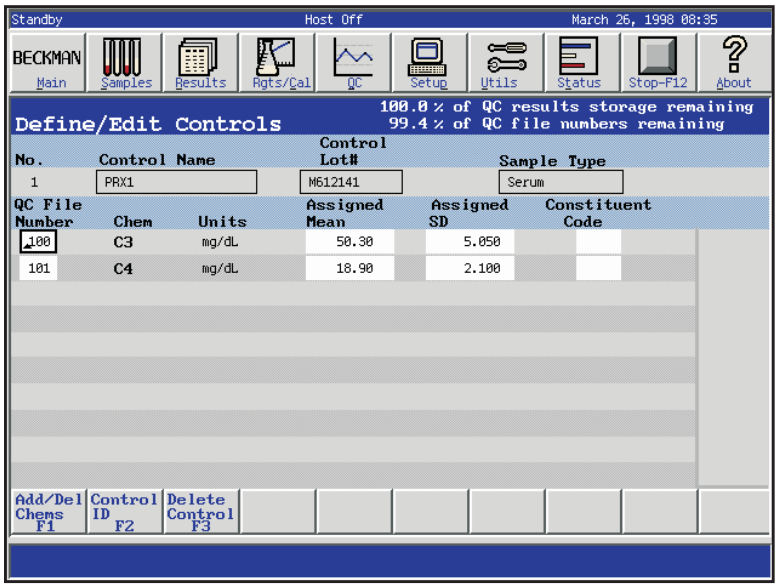
Each laboratory should establish its own precision parameters which more accurately reflect individual laboratory quality control criteria.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.



E014029S.EPS

Figure 9.1 Quality Control Screen



E014031S.EPS

Figure 9.2 Define/Edit Controls Screen

CAUTION

When creating *Control* IDs, use a format that is distinctly different from *Sample* IDs. This will prevent the reporting of erroneous results due to controls being run as patient samples, or patient samples being run as controls.

The Control ID dialog box will display. Up to eight unique IDs, each with a maximum of 15 alphanumeric characters may be entered.

CHAPTER 10 Utilities

Maintenance

Daily Maintenance Procedures

The following table lists the scheduled daily maintenance for the IMMAGE 800 System.

Table 10.1 Daily Maintenance

Check	Clean
Wash Volume and Tubings	Reagent and Sample Probes/Mixers
Waste Volume and Tubing	
Fluid spills	
Syringes: tubings, tips, and valves	

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Monthly Maintenance Procedures

The following table lists the scheduled monthly maintenance for the IMMAGE 800 System.

Table 10.2 Monthly Maintenance

Check	Perform
Exterior surfaces	Record the cycle count
Fan Filters	

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

As-Indicated Maintenance

The following table lists the As-Indicated maintenance for the IMMAGE 800 System.

Table 10.3 As-Indicated Maintenance

Check	Perform
Clean or replace printer cartridge (Refer to Printer Manual.)	Replace all Cuvettes every 10,000 tests. For systems using DIL2, cuvettes may need to be replaced more frequently. (Refer to IMMAGE Immunochemistry Systems *Chemistry Information Manual*, Appendix F for chemistries using DIL2.)
Decontaminate Sample/Reagent Carousels and Sample Racks	Cuvette Wash.
	Replace syringes if leaking occurs, or as needed.
	Replace UPS battery when "battery low" light or audible alarm is activated. (Refer to UPS User's Manual.)

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Troubleshooting

Error Messages

The following table describes the types of error messages generated by the system. Error messages contain an explanation of the problem as well as an error number for reference in the Error Table. Errors are also logged in the Event log. For retrieval of events, refer to Event Log in this section.

Table 10.4 Error Messages

Location	Explanation
Remarks column of patient report	System is unable to obtain a valid answer.
Instrument errors on patient report	A code to indicate that the system is operating in a user-modified mode.
Green border pop-up window on screen	INFORMATIONAL MESSAGE only.
Yellow border pop-up window on screen	WARNING MESSAGE, system performance may need to be reviewed. Operation will continue unless startup checks have failed.
Red border pop-up window on screen	FATAL WARNING message, system performance must be reviewed and operation will cease.

Error Table

The Error Table is useful to look up an explanation of any displayed or printed error messages.

- Error messages with the prefix "E" are found on patient reports (e.g., E10).
- Error messages without a prefix are displayed as pop-up windows (e.g., 10).

The "Action" column is prioritized with the most likely solutions appearing first. Call Beckman Coulter Clinical Support as a final resolution.

> NOTICE
> The Status Monitor screen updates every three seconds with out-of-range results highlighted in red and should, therefore, be observed for several minutes to verify proper instrument performance.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details and Error Tables.

Event Log

The Event Log is a record of system events, such as an error or system status information that is logged, (e.g., "The time has changed"). This logged information can be used as a troubleshooting tool if a problem is encountered while operating the instrument.

To access the Event Log, select **Utilities** from the menu bar. (Refer to Figure 10.1.) Select **<2> Event Log**.

> NOTICE
> It may be useful to select a specific time period for retrieval. This may be done before or after selecting the event option number. Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details on **Date/Time** option instructions.

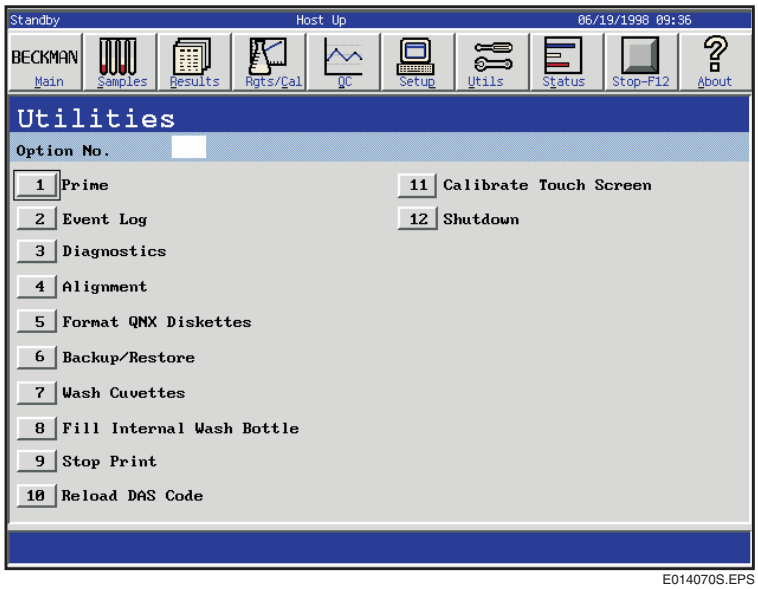


Figure 10.1 Utilities Dialog Box

Callable Diagnostics

The Callable Diagnostics option provides procedures directed toward identifying and isolating specific IMMAGE 800 malfunctions.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Alignment

The Alignment option contains procedures for alignment for the IMMAGE 800. Alignment procedures are performed on hardware components classified into different Functional Areas.

Backup/Restore

The Backup/Restore option provides the ability to store data to a floppy disk or hard disk for use at a later time.

Backup saves data to the hard disk or to a diskette for safe storage.

Restore takes previously backed up data from the hard disk or diskette and places it back onto the system.

The instrument status must be *Standby* in order to proceed with the steps below to back up or restore data.

To backup/restore, select **Utilities** from the menu bar and then select **<6> Backup/Restore**.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Fill Internal Wash Bottle

The IMMAGE 800 is equipped with an internal wash bottle that supplies wash solution to the system where needed.

The internal wash bottle is pressurized and is constantly replenished with wash solution from the Wash Solution Container, P/N 447060. When the source runs out of wash solution, it may be necessary to fill the internal wash bottle after replacing the empty Wash Solution Container.

To fill the internal wash bottle, select **Utilities** from the menu bar and then select **<8> Fill Internal Wash Bottle**.

NOTICE

The level of wash solution in the internal wash bottle can be verified through the Instrument Status Monitor.

Calibrate Touch Screen

The IMMAGE 800 system can access screen components with the optional touch screen monitor. After calibration of the touch screen, software functions can be activated by the touch of a finger or other object. Any icon, button, or field on the screen can be selected by touching the icon, button, or field on the screen.

To calibrate touch screen, select **Utilities** from the menu bar and then select **<11> Calibrate Touch Screen**.

Replacing Parts/User Servicing

The customer-replaceable parts on the IMMAGE 800 are:

- Syringe
- Sample and Reagent Crane Mixer/Paddle
- Sample and Reagent Crane Probe.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

CHAPTER 11 System Status/Instrument Commands

System Status/Instrument Commands

Checking Dilution Segment Status and Clearing Dilution Segments

Prior to starting every run, the Dilution Segments status should be checked. There are two options from the Dilution Segments dialog box:

- The status of the dilution segments can be left unchanged.
- Up to four dilution segments can be cleared. The cleared segments must be replaced with unused segments on the sample carousel.

To check status and clear segments, select **Status** from the menu bar, and then select **<1> Dilution Segments**. (Refer to Figure 11.1.)

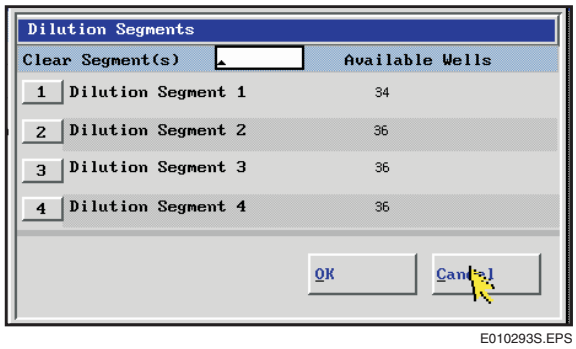


Figure 11.1 Dilution Segments Dialog Box

Always replace the cleared dilution segments with unused segments on the sample carousel before a run is started.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Checking Sample Carousel Status

The status of each sample on a run can be monitored during the run through Sample Carousel Status. The status is indicated by the colored indicator beside the Position Number/Sample ID.

To access sample carousel status, select **Status** from the menu bar, the select **<2> Sample Carousel Status**.

Description of Sample Carousel Status

The following table describes the sample carousel status indicator colors and sample carousel status terms.

Table 11.1 Sample Carousel Status

Indicator Color	Status	Description
White	Not Programmed	Sample is not programmed or saved.
Purple	Host Query	Sample ID queries the host for programming.
Yellow	Waiting to Run	The sample carousel was scanned and the sample program is recognized by the system.
Green	Running	One or more tests requested for the sample are running.
Red	Incomplete	At least one test result for the sample is pending.
Blue	Complete	All tests requested for the sample are complete.

The sample bar code reader will read either the sample bar code label or the background bar code label on the rack. After a bar code is read, the database is checked for a program.

Refer to the IMMAGE 800 Immunochemistry System *Operations Manual* for further details.

Checking the Instrument Status Monitor

The instrument status monitor displays the instrument parameters which are continuously monitored.

To access instrument status monitor, select **Status** from the menu bar, and then select **<3> Instrument Status Monitor**.

Parameters which are out of range display in red.

APPENDIX A Additional Information

Pre-run Checklist

With the IMMAGE® 800 in *Standby*, prepare for the start of a run by performing these tasks or verifying they have been performed. Refer to appropriate sections of this Instructions For Use for information on how to perform each task.

- Perform daily maintenance
- Check status of dilution segments, clear and replace if necessary.
- Check status of reagent cartridges, load if necessary.
- Check status of reaction buffers and sample diluents, replace if necessary.
- Check sample rack status, clear racks if necessary.
- Check calibration status, calibrate if necessary.
- Prepare sample containers.
- Program control or patient requests, if necessary.
- Load samples.

Quick References Using the IMMAGE 800 Immunochemistry System Operations Manual

Table A.1 Quick References

Topic	Location in Operations Manual
Antigen excess testing	**CHAPTER 3** ***Theory of Operations***
Bar codes	**CHAPTER 2** ***System Description*** Sample Container Information, Bar Code Types and Options, Bar Code Label Specifications, Applying Bar Code Labels
Batch programming	**CHAPTER 7** ***Sample Programming*** Programming a Batch of Samples
Boot	**CHAPTER 4** ***System Power On/Off***
Calibration bar coded parameters	**CHAPTER 6** ***Reagents/Calibration*** Reagents, Loading Reagent/Calibrator Bar Coded Parameters
Calibration curves	**CHAPTER 3** ***Theory of Operations***
Calibration History	**CHAPTER 6** ***Reagents/Calibration*** Calibration, Calibration History
Cuvettes, replacing	**CHAPTER 10** ***Utilities*** Maintenance, As-Indicated Maintenance
Cuvettes, washing	**CHAPTER 10** ***Utilities*** Maintenance, As-Indicated Maintenance
Cycle count	**CHAPTER 10** ***Utilities*** Maintenance, Monthly Maintenance Procedures
Date and time changes	**CHAPTER 5** ***System Setup*** System Software Configuration, Date and Time Setup
Decontaminate carousels and racks	**CHAPTER 10** ***Utilities*** Maintenance, As-Indicated Maintenance

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Table A.1 Quick References, continued

Topic	Location in Operations Manual
Dilutions, off-line	**CHAPTER 7** ***Sample Programming*** Programming a Sample, Entering an Off-line Dilution Factor
Error messages	**CHAPTER 10** ***Utilities*** Troubleshooting, Errors
Fan filters, cleaning	**CHAPTER 10** ***Utilities*** Maintenance, Monthly Maintenance Procedures
Glossary	Back of Operations Manual, before the Index
Host communication	**CHAPTER 5** ***System Setup*** System Software Configuration, Host Communications Setup
Host Communications Setup	**CHAPTER 2** ***System Description*** Instrument Operation Overview
Instrument codes	**APPENDIX B**
Linking samples for special calculations	**CHAPTER 7** ***Sample Programming*** Programming a Sample, Linking/Unlinking Samples
Loading Samples	**CHAPTER 7** ***Prepare for Programming/Running*** Loading and Starting a Run, Loading Samples
Non-Standard Default Dilution	**CHAPTER 5** ***System Software Configuration*** Selecting Non-Standard dilutions as Default for Each Chemistry
Off-line Dilutions	**CHAPTER 7** ***Prepare for Programming/Running*** Programming a Sample, Entering an Off-line Dilution Factor
Password Protection	**CHAPTER 5** ***System Software Configuration*** Setting Up a UDR Chemistry, Password Setup Procedure
Pause	**CHAPTER 7** ***Prepare for Programming/Running*** Pausing a Run, System Pause, Pausing to Load Samples
Part numbers for ordering supplies	**APPENDIX A**

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Table A.1 Quick References, continued

Topic	Location in Operations Manual
Post-run summary	**CHAPTER 7 *Sample Programming*** Requesting a Load List or Post-run Summary, Requesting a Post-run Summary
Power on/off	**CHAPTER 4 *System Power On/Off***
Pre-run Check List	**CHAPTER 7 *Prepare for Programming/Running*** Programming a Sample, Pre-run Check List
Principles of methodologies	**CHAPTER 3 *Theory of Operations***
Quality control	**CHAPTER 9 *Quality Control***
Rack label placement	**CHAPTER 5 *System Setup*** Instrument Setup, Placing Labels on a Rack
Reagent bar coded parameters	**CHAPTER 6 *Reagents/Calibration*** Reagents, Loading Reagent/Calibrator Bar Coded Parameters
Recalling results	**CHAPTER 8 *Results Recall***
Report format examples	**APPENDIX C**
Rerun samples	**CHAPTER 7 *Sample Programming*** Rerunning a Sample
Robust Means Data	**CHAPTER 5 *System Software Configuration*** Approving a Calibration, Plotting a Robust Means Data Curve
Sample tubes and cups	**CHAPTER 2 *System Description*** Sample Container Information, Sample Containers Allowed
Software overview	**CHAPTER 2 *System Description*** Software Overview
Surfaces, cleaning	**CHAPTER 10 *Utilities*** Maintenance, Monthly Maintenance Procedures
Symbols and labels on the IMMAGE	**CHAPTER 1 *General Information/Precautions and Hazards*** Symbols and Labels
Syringes, replacing	**CHAPTER 10 *Utilities*** Maintenance, As-Indicated Maintenance

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Table A.1 Quick References, continued

Topic	Location in Operations Manual
Volume requirements for samples	**CHAPTER 2** ***System Description*** Sample Container Information, Sample Volume

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Sample volumes

Use the IMMAGE Immunochemistry Systems Sampling Template to verify volumes.

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